I. GENERAL PROVISIONS

Subject of regulation

Article 1

This Law shall regulate the matters related to the system and organization of health protection and
the performance of healthcare activity, the guaranteed rights and the established needs and interests
of the country in the provision of health protection, the healthcare institutions, the employment, rights
and duties, responsibility, assessment, termination of employment, protection and decision-making
upon the rights and obligations of healthcare workers and healthcare co-workers, the quality and
safety of healthcare activity, the chambers and professional associations, the marketing and
advertising of healthcare activity, the performance of healthcare activity in case of emergencies, and
the supervision of the performance of healthcare activity.

Definition of health protection

Article 2

(1) The health protection, in terms of this Law, shall include a system of social and individual
measures, activities and procedures for:
- maintenance and promotion of health,
- prevention, early detection and eradication of diseases, injuries and other work- and environment-
related health disorders,
- timely and efficient treatment, and
- healthcare and rehabilitation.

(2) The measures, activities and procedures referred to in paragraph (1) of this Article must be based
on scientific evidence, must be safe, secure, efficient and in accordance with the professional ethics.

Right to health protection

Article 3

(1) Everyone shall be entitled to health protection and shall be obliged to care for and maintain and
promote his/her health in accordance with this and another law.

(2) No one must endanger the health of the others.

(3) In states of emergency, everyone shall be obliged to provide first aid according to his/her abilities,
and in a life-threatening situation, to notify the closest healthcare institution and to enable access to
emergency medical care.

Human rights and values in the health protection

Article 4
(1) Every citizen shall have the right to be provided health protection that observes the highest possible standard of human rights and values, that is, he/she shall have the right to physical and psychological integrity and safety of his/her personality, as well as to respect for his/her moral, cultural, religious and philosophical convictions.

(2) Every citizen shall be entitled to information required for maintaining the health and for attaining healthy lifestyles and to information about the harmful factors of the living and working environment which may have a negative impact on the health, as well as to information about the measures necessary for health protection in case of epidemics and other disasters and accidents which may have a negative impact on the health.

Health protection principles

Article 5

The health protection shall be based on the unity of preventive, diagnostic and therapeutic, and rehabilitation measures and on the principles of accessibility, efficiency, continuity, fairness, comprehensiveness and provision of quality and safe health treatment.

Principle of accessibility

Article 6

The principle of accessibility of health protection shall be attained by providing appropriate health protection for the population of the Republic of Macedonia, which is geographically, physically and economically accessible, and particularly the health protection at primary level.

Principle of efficiency

Article 7

The principle of efficiency of health protection shall be attained by achieving the best possible results with respect to the available means, that is, by achieving the highest level of health protection with the least means used.

Principle of continuity

Article 8

The principle of continuity of health protection shall be ensured by functionally implemented organizational system of healthcare activity at all levels of health protection starting from the primary, through the secondary, up to the tertiary level, in a manner which provides continuous health protection of the population at any time.

Principle of fairness

Article 9

The principle of fairness in health protection shall be attained by prohibition of discrimination in the provision of health protection with regard to race, gender, age, nationality, social background, religious belief, political or other convictions, property status, culture, language, type of disease, mental or physical disability.
**Principle of comprehensiveness**

**Article 10**

The principle of comprehensiveness of health protection shall be ensured by the inclusion of each individual in the health protection system, by applying measures and activities for health protection that include health promotion, prevention of diseases at all levels of health protection, early diagnostics, treatment and rehabilitation.

**Principle of quality and safe health treatment**

**Article 11**

The principle of quality and safe health treatment shall be provided by advancing the quality of health protection by applying measures and activities that, in accordance with the contemporary achievements in the field of medical science and practice, increase the possibility for positive outcome, decrease the risks and the other adverse consequences to the health and the health condition of the individual and the society as a whole.

**Healthcare activity**

**Article 12**

(1) The healthcare activity shall be an activity of public interest.

(2) Healthcare activity shall be a public service activity which ensures health protection and which covers the measures, activities and procedures that, in accordance with the evidence-based medicine and with the use of health technology, are applied for maintenance and promotion of the health, for prevention, early detection and eradication of diseases, injuries and other work- and environment-related health disorders, for timely and efficient treatment, as well as for health care and rehabilitation.

(3) The healthcare activity shall be provided at primary, secondary and tertiary level of health protection.

(4) Health services shall be provided by healthcare workers, and particular activities within the healthcare activity may be provided by healthcare co-workers who meet the requirements under this and another law.

(5) The healthcare activity shall be performed in healthcare institutions.

(6) As an exception to paragraph (5) of this Article, a healthcare activity may also be performed in other legal entities referred to in Article 96 of this Law under conditions determined by law.

**Performance of healthcare activity**

**Article 13**

(1) The healthcare activity shall be performed in a network of healthcare institutions and outside the network of healthcare institutions.
(2) The Republic of Macedonia shall be competent for exercising the health protection in the network of healthcare institutions, where the healthcare activity is performed under the conditions determined by this Law.

(3) The healthcare activity in the network shall be performed by public and private healthcare institutions, which perform the activity on the basis of a license.

(4) The healthcare activity outside the network shall be performed by private healthcare institutions under conditions determined by this Law and shall be financed by the health services which the patients are paying with their own funds.

**Rights under employment in a public healthcare institution**

**Article 13-a**

The positions of the employees in the public healthcare institutions shall be divided in groups and subgroups in accordance with the Law on Public Sector Employees:
- administrative servants,
- providers of public health services, and
- auxiliary-technical persons.

**Salaries of employees in public healthcare institutions**

**Article 13-b**

The salaries of the employees in the public healthcare institutions shall be determined by the collective agreements in accordance with the type of required professional qualifications and job competencies, the responsibility, the type and complexity of the works and tasks, as well as in accordance with the other criteria of importance for the job.

**Rights and duties of the patient**

**Article 14**

Every patient shall have rights and duties determined by this and another law.

**Definitions of the terms**

**Article 15**

The terms used in this Law shall have the following meaning:

1. “Public health” is a system of knowledge and skills for prevention of diseases, continuation of life and promotion of health through organized efforts of the society;

2. “Acute treatment” is a healthcare treatment of a sudden disease, injury or sudden deterioration of a chronic disease;

3. “Obstetrics care” is a treatment for women during pregnancy, delivery and post-delivery period, as well as for the newborn and the infant by midwives with the purpose of preserving or reaching their best health, as well as work in particular areas of gynecology and family planning;
4. “Type of healthcare activity, that is, specialty” is a more narrow area of healthcare activity, that is, specialty at a particular lever of health protection;

5. “Day hospital” is a manner of treatment of the patient, which does not require a stay in a hospital for more than 8 hours per day in order to be provided with the health services for diagnostics, therapy, care and rehabilitation performed at the secondary level;

6. “Agreement with the Health Insurance Fund of Macedonia” is an agreement between the Health Insurance Fund of Macedonia and the healthcare institution in the network, whereby they agree upon the scope and type of health services that the healthcare institution in the network is to provide in a particular period, in accordance with the regulations in the field of mandatory health insurance;

7. “Healthcare worker” is a person who provides health services in the delivery of a particular healthcare activity and is entered in the register of healthcare workers (doctor of medicine, doctor of dental medicine and pharmacist who holds a university degree or who have completed academic integrated studies with 300, that is, 360 ECTS in the field of medicine, dental medicine and pharmacy, healthcare workers with a two-year post-secondary school or higher vocational education or with 180 ECTS in the field of medicine, dental medicine and pharmacy) and healthcare workers who hold a high school degree;

8. “Healthcare co-worker” is a person who holds a university degree and independently carries out particular activities within the healthcare activity in cooperation with the healthcare workers;

9. “Health treatment” are health services that fully cover specific needs of the patient in view of prevention, treatment and rehabilitation of diseases and injuries or preservation of the mental and physical health;

10. “Health care” is an activity that treats the individual, the family and its surrounding in states of health and illness, for the purpose of achieving as high level of health as possible and to make possible for the patients to independently perform the basic life functions, promotion of their health, care of the ill and participation in the process of treatment, rehabilitation and palliative care;

11. “Health technology” are all the healthcare methods and procedures which can be used for promotion of the health, prevention, diagnostics and treatment of diseases, injuries and rehabilitation, which include safe, quality and efficient medicaments and medical devices, medical procedures, as well as conditions for provision of health protection;

11-a. "New healthcare methods or procedures" are healthcare methods or procedures that may be used for improvement of the health, the prevention, the diagnostics, and the treatment of diseases, injuries and the rehabilitation, and that, until the moment of their introduction, have not been used in the internal organizational unit of the public healthcare institution at secondary level and/or tertiary level, that is, in the public healthcare institution at secondary and/or tertiary level as a whole, or are used in the health system of the Republic of Macedonia for the first time;

12. “Health service” is a separate activity or a procedure within the healthcare treatment of the patients provided by healthcare workers;

13. “Healthcare institution in a network” are public healthcare institutions and private healthcare institutions which perform an activity on the basis of a license and which perform the healthcare activity within the network of healthcare institutions;

14. “Emergency medical care” is provision of urgent health services which, if not provided within a short period of time, could cause irreparable and severe damage to the health of the patient or death;
15. "Clinical pathway" is a previously determined description of the course of the healthcare treatment of the patients with a particular health condition in the healthcare institution;

16. “Chamber” is an association of healthcare workers established in accordance with this Law, where the healthcare workers are associated for the purpose of achieving and representing mutual interests of a particular occupation;

17. "Laboratory activity" is a branch of medicine examining samples of tissues, liquids and other bodily substances outside the human body for the purpose of obtaining data on the health condition, the cause of the disease and the course of the treatment and the prevention;

18. "License for work” is a public document which proves the professional qualifications of the healthcare worker for providing health services;

19. “Network of healthcare institutions” is the determination of the necessary number of healthcare institutions and the types of healthcare activity, that is, specialty provided in particular geographic areas according to the place of residence of the health protection beneficiaries, and that are to be provided in accordance with the needs for health protection of the population on the territory of the Republic of Macedonia;

20. "Non-profitability of the performance of healthcare activity in the network” means that the entire surplus of income over expenditure of healthcare institutions in the network is to be earmarked for development of health services and healthcare activity;

21. “Level of healthcare activity” is organization of the healthcare activity at primary, secondary and tertiary level of health protection, depending on its tasks and complexity;

22. “Holder of healthcare activity” is a healthcare worker who holds a university degree in the field of medicine, dental medicine and pharmacy with an appropriate license for work;

23. "Responsible holder of healthcare activity in the institution” is a healthcare worker who is responsible for the professional provision of health services for the particular type of healthcare activity, that is, specialty in the healthcare institution;

24. “Palliative care” is active, complete assistance for patients with progressive terminal disease and assistance for their closest ones in the course of the disease and in the grieving period;

25. “Pathoanatomical activity” is determination and study of the morphological and functional change which is caused by the process of the disease in the cells, tissues and organs;

26. "Patient” is a person, sick or healthy, who seeks or who undergoes a particular medical intervention for the purpose of preserving and promoting the health, preventing diseases and other health conditions, treatment or health care and rehabilitation;

27. "Area” is a geographically determined area of one or several local self-government units for which a network of healthcare institutions is established at a particular level of performance of healthcare activity;

28. “Marketing of the healthcare activity” are marketing messages and other forms of information as a marketing element the final purpose of which is the use of the health service;

29. “Reference center” is a healthcare institution or its unit, oriented towards treatment of rare diseases or complex diagnostic and therapeutic procedures, which is awarded the status for the specific field on the basis of a multi-year experience and demonstrated achievements;
30. “Rehabilitation” is a health treatment aimed at renewal or substitution of physical, mental and social capacities of the patient that are inborn, that is, caused by a disease, that is, injury;

31. “Professional associations” are associations of healthcare workers in the field of medicine, dental medicine and pharmacy, that represent their professional interests;

32. “Professional instruction” is a set of systematically developed conclusions on the successfullness and efficiency of the methods and procedures for treating a particular health condition, which are based on the assessment of the evidence for the most appropriate methods of health treatment of patients (evidence-based medicine);

33. “Telemedicine” is an exchange of medical information through information and communication technology for the purpose of improving the healthcare treatment of the patient in the field of diagnostics, treatment and monitoring the patient, as well as in the field of professional exchange of opinions;

34. “Healthcare team” is a group of medical nurses and other healthcare workers who provide health care and attention for the patients, headed by a medical nurse;

35. “Team” is a group of healthcare workers that ensures performance of a healthcare activity within the scope of its responsibility in the healthcare institution in the network at a particular level of healthcare activity;

36. “Pharmacists” is a person holding a bachelor’s or master’s degree in pharmacy;

37. “Pharmaceutical activity” is a part of the healthcare activity that includes uninterrupted, continuous supply of medicaments and medical devices, their production, manufacturing, distribution and control, information, advise, consulting and education of the patients and healthcare workers about rational and efficient use of medicaments and medical devices, and monitoring of the effects of the use of medicaments;

38. “Quality of health protection” are measures and activities which, in accordance with the contemporary achievements in the medical, dental and pharmaceutical science and practice, as well as the knowledge and skills of the healthcare workers, increase the possibilities for the most favorable possible outcome of the treatment and decrease the risks of advert consequences upon the health and health condition of the individual and the community as a whole;

39. “Internal quality control” is a systematic control of professional activities in the healthcare institutions with regard to the prescribed standards; and

40. “External quality control” is a process of external assessment of the quality of health services which compare the provision of the health services in the healthcare institution to the published standards, thus identifying the possibilities for improvement of the quality of the health services.

II. GUARANTEED RIGHTS AND ESTABLISHED NEEDS AND INTERESTS OF THE STATE IN THE PROVISION OF HEALTH PROTECTION

Ensuring the exercise of the guaranteed rights, established needs and interests by the Republic of Macedonia

Article 16
(1) All the citizens of the Republic of Macedonia shall be ensured the exercise of the rights, the established needs and interests guaranteed by this Law, that is:
- measures and activities for protection against the harmful impact of gasses, noise, ionizing and non-ionizing radiation, pollution of the water, soil, air and food on the health of the population, and the other harmful impacts on the living and working environment,
- measures and activities for maintenance of the health of the population,
- measures and activities for detection, prevention and eradication of communicable diseases,
- provision of hygienic and epidemiological minimum of the population,
- prevention and treatment of quarantine diseases and drug addiction,
- measures and activities for protection of women during pregnancy, delivery and breastfeeding and protection of the infants,
- measures and activities for organization and promotion of blood donation,
- coverage of the costs for people on dialysis,
- provision of medicaments for patients with transplants,
- provision of cytostatics, insulin and growth hormone,
- measures and activities determined by special programs, and
- emergency medical care in accordance with the established network of healthcare institutions.

(2) The measures and activities referred to in paragraph (1) line 11 of this Article shall be determined on the basis of the health condition of the population and the established health problems and priorities of public health nature in accordance with the adopted strategies and policies in the field of health protection.

(3) The Government of the Republic of Macedonia (hereinafter: the Government) on a proposal of the Ministry of Health shall adopt programs for implementation of the measures and activities referred to in paragraph (1) of this Article on an annual basis.

(4) The funds for exercising the guaranteed rights and the established needs and interests of the state referred to in paragraph (1) of this Article shall be provided from the Budget of the Republic of Macedonia and from a part of the beer excise in the amount of 1 Denar per liter/percentage of alcohol and from a part of the ethyl alcohol excise in the amount of 40 Denars per liter pure alcohol.

(5) The excise referred to in paragraph (4) of this Article shall be considered revenue of the Budget of the Republic of Macedonia – Ministry of Health and shall be paid at a corresponding account of the Ministry of Health within the treasury account.

(6) The part of the excise referred to in paragraph (4) of this Article shall be calculated by the Customs Administration in the course of collecting the beer and ethyl alcohol excise and it shall pay it at a corresponding account of the Ministry of Health within the treasury account.

**Network of healthcare institutions**

**Article 17**

(1) The network of healthcare institutions (hereinafter: the network) in accordance with this Law, shall determine:
- the types of healthcare activity that are provided in particular geographic areas according to the place of residence of the beneficiaries of health protection,
- the personnel, spatial and accommodation capacities of the hospitals for provision of particular type of healthcare activity, that is, specialty,
- the type and number of technically complex diagnostic equipment, and
- the spatial plan for performance of the healthcare activity, including definition of the type and scope of the health services.

(2) The network referred to in paragraph (1) of this Article shall be composed of a network of healthcare institutions at:
- primary level of health protection for performance of the activities within the primary health protection and pharmaceutical activity,
- secondary level of health protection for performance of specialist, consultative, and hospital healthcare activity,
- tertiary level of health protection for performance of the most complex health services within the specialist, consultative, and hospital healthcare activity which are not possible or are not recommended to be performed at the lower levels of healthcare activity.

(3) The network referred to in paragraph (1) of this Article shall be established by the Government on the basis of the following criteria:
- needs for health services of the population,
- number, age, gender, social structure and health condition of the population in the area where the network is being established,
- provision of equal accessibility of health services, particularly for outpatient treatment and emergency medical care,
- minimum number of health services per healthcare institution required for maintenance of the quality and safety of the practical skills and experiences,
- ensuring the central role of the primary health protection,
- separation of the work of the healthcare activity at primary, secondary and tertiary level of health protection,
- provision of healthcare capacities, in accordance with the scope of the rights under the mandatory health insurance and economic justifiability,
- technological and scientific development in the field of healthcare activity;
- urbanization degree of the areas, specifics of the population, traffic connections, migrations of the population and accessibility to the healthcare institutions, and special conditions of demographically endangered areas.

(4) The Government shall establish the standards for ensuring capacities in the network, depending on the number of citizens or groups of citizens according to the age and gender per:
- particular holder of a healthcare activity,
- hospital bed and particular specialty, and
- technically more complex unit, that is, equipment.

(5) In establishing the standards referred to in paragraph (4) of this Article, the Government may request an opinion from the Fund.

(6) Depending on the condition of the premises, the equipment and the personnel, the Government shall adopt a Strategy for Establishment of a Long-term Schedule for Adjustment of the Actual Capacities to the Standards that are determined in paragraph (4) of this Article.

(7) The Ministry of Health shall monitor the functioning and the maintenance of the network and shall continuously harmonize the data and the number of healthcare institutions in the network in accordance with the changes in the data and the number of healthcare institutions in the network and shall post them on the website of the Ministry of Health.

(8) Each introduction of a new health technology and equipment, as well as each introduction of new healthcare methods or procedures, in the healthcare institutions in the network shall be subjected to a previous approval by the Ministry of Health, based on an analysis of the medical, ethical, social and economic consequences and effects from the development, expanding or use of the new health technology and equipment in the provision of health protection.

(9) The data on the personnel, premises, hospital beds and diagnostic equipment in the network shall be kept and analyzed by the Institute for Public Health of the Republic of Macedonia, in accordance with the regulations in the field of health records.

**Distribution of the performance of the healthcare activity in the network**
Article 18

(1) The distribution of the performance of the healthcare activity in the network among the primary, secondary and tertiary level of health protection (hereinafter: distribution of the performance of the healthcare activity) shall be determined by the Government, on a proposal of the minister of health.

(2) The professional associations and the chambers in the field of health shall render their opinion upon the proposal of the minister of health regarding the distribution of the performance of the healthcare activity referred to in paragraph (1) of this Article.

Network at primary level of health protection

Article 19

(1) The network at primary level of health protection (hereinafter: the primary level) shall be divided in separate geographic areas that may cover one or several municipalities, in accordance with the criteria referred to in Article 17 paragraph (3) of this Law.

(2) Each area referred to in paragraph (1) of this Article shall be ensured the performance of all types of healthcare activity at primary level, that is, specialty that, in accordance with the distribution of the performance of the healthcare activity, is provided at primary level in a medical center and in private healthcare institutions that perform healthcare activity on the basis of a license at primary level in the network.

Network at secondary level of health protection

Article 20

(1) The network at secondary level of health protection (hereinafter: the secondary level) shall be divided into separate geographic areas defined in accordance with the regulations in the field of statistics and shall consist of a network of specialist and consultative activity and a network of hospital healthcare activity.

(2) The contents and the scope of the specialist and consultative activity referred to in paragraph (1) of this Article shall be determined at state level, starting with the need of particular accessibility of the activity, which at the same time has to be professionally and financially sustainable.

(3) Specialist and consultative healthcare activity which is provided in a medical center at primary level shall be a part of the network at secondary level.

(4) In determining the contents and the scope of the network of hospital healthcare activity referred to in paragraph (1) of this Article, it shall be taken into consideration that the activity must be provided 24 hours a day, every day in the year and must be professionally and financially sustainable.

(5) The network of hospital healthcare activity at secondary level shall determine in particular the activities that, due to the complexity of their performance, the equipment required, and the need of extended medical supervision, may be efficiently provided only in particular hospitals, in accordance with the criteria set out in Article 17 paragraph (1) of this Law.

Network at tertiary level of health protection

Article 21
The network at tertiary level of health protection (hereinafter: the tertiary level) shall be determined in accordance with the criteria for performance of health services that require expert, organizational and technologically complex and multidisciplinary healthcare treatment laid down in Article 17 paragraph (1) of this Law.

Network of emergency medical care

Article 22

(1) The network of emergency medical care, including the distribution of emergency medical care units at all levels of health protection shall be determined by the Government, on a proposal of the minister of health, in accordance with Article 18 of this Law.

(2) Units for emergency dental care for acute treatment of dental cases in third shift, as well as during holidays, non-working days and weekends, may also be planned within the network referred to in paragraph (1) of this Article, depending on the needs of the population in a particular area.

Network of labor medicine

Article 23

(1) The network of labor medicine at all levels of health protection, on a proposal of the minister of health, shall be established by the Government and it shall be consisted of private and public healthcare institutions that practice labor medicine, the expert work of which is coordinated by the Public Healthcare Institution – Institute of Labor Medicine of the Republic of Macedonia, in accordance with this Law and the regulations in the field of public health.

(2) The list of authorized public and private healthcare institutions that practice labor medicine shall be published on the website of the Ministry of Health.

Public health network

Article 24

The public health network shall be composed of public healthcare institutions – centers of public health that carry out public health activity at all levels of health protection, the expert work of which is coordinated by the Public Healthcare Institution – Institute of Public Health of the Republic of Macedonia.

Funds for performance of the healthcare activity in the network

Article 25

(1) The funds for performance of the healthcare activity in the network shall be provided from:
1) the Budget of the Republic of Macedonia;
2) the Health Insurance Fund of Macedonia (hereinafter: the Fund);
3) participation of the insured with own funds, in accordance with the regulations in the field of mandatory health insurance; and
4) health services which are covered by the patients by their own funds under conditions established by law.

(2) The funds referred to in paragraph (1) point 1 of this Article shall be provided for achieving the guaranteed rights and the established needs and interests determined by the programs referred to in
Article 16 paragraph (1) of this Law and for establishing new, and ensuring investments in, facilities and equipment in the existing public healthcare institutions.

(3) The funds referred to in paragraph (1) points 2 and 3 of this Article shall be provided for exercising the rights of the insured persons under the mandatory health insurance.

(4) In addition to the funds referred to in paragraph (1) of this Article, the healthcare institutions in the network may also provide funds from:
- performance of healthcare activity for patients who cover the health services by own funds in accordance with Article 44 of this Law,
- provision of health services as additional activity in accordance with Article 223 of this Law, and
- other sources in accordance with this and another law.

(5) The funds for performance of healthcare activity in the labor medicine network shall also be provided from the health services that the employers are obliged to provide for their employees in accordance with the regulations on safety and health at work.

III. HEALTHCARE ACTIVITY

Contents of the healthcare activity

Article 26

(1) The healthcare activity, in terms of this Law, shall include:
- implementation of measures and activities for protection, promotion and improvement of the health and for early detection of diseases,
- early detection of the risk factors for causing chronic diseases and their control and screening services, in accordance with the programs referred to in Article 16 of this Law;
- health services in the field of public health;
- specific preventive health measures for prevention of communicable diseases and their spreading,
- programs for protection of sexual and reproductive health,
- determination of diseases, treatment and medical rehabilitation of patients,
- dental preventive, curative and prosthetic activity,
- health services concerning the safety and health at work, in the traffic and during sports activities and other health services provided in accordance with special regulations,
- telemedical activity,
- medical laboratory activity,
- radiological and other functional diagnostics,
- in-house health treatment of patients and treatment within social protection institutions;
- emergency medical care,
- life-saving transports,
- palliative care,
- examination of deceased persons,
- pathoanatomical forensic activity,
- supply of blood and blood components;
- procedures for harvesting and storing gametes,
- biomedical assisted insemination procedures,
- harvesting and transplanting human body parts as treatment,
- expert forensic procedures required by the social insurance funds,
- pharmaceutical activity,
- services of certain complementary, alternative and/or traditional forms of treatment and rehabilitation, provided by healthcare workers in accordance with the law, and
- other healthcare activity that in accordance with this Law is performed by the healthcare institutions.
(2) Particular activities, that is, health services referred to in paragraph (1) of this Article shall be performed solely on the basis of an authorization by the minister of health, in accordance with this and another Law.

(3) The lists of health services and the coefficients of complexity of health services for establishing the results of the work of healthcare workers, determined on the basis of the complexity and the duration of the health service and the possibility of complications per levels of health protection that may be performed within special activities and types of healthcare institutions shall be determined by the minister of health.

**Instructions for evidence-based medicine**

**Article 27**

(1) The healthcare activity in the healthcare institutions shall be mandatorily carried out by healthcare workers and co-workers in accordance with professional instructions for evidence-based medicine which, in line with the modern medical practice, shall be determined by the minister of health.

(2) The Health Insurance Fund as purchaser of health services shall give prior opinion regarding the professional instructions referred to in paragraph (1) of this Article from the financial aspect.

(3) Supervision over the performance of the healthcare activity in accordance with the professional instructions referred to in paragraph (1) of this Article shall be conducted by the Ministry of Health and the State Sanitary and Health Inspectorate, as well as the Health Insurance Fund of Macedonia regarding the financing of the provision of health services.

(4) The healthcare activity in the healthcare institutions from the organizational aspect shall be mandatorily performed in accordance with the protocols determined by the minister of health.

**1. Performance of healthcare activity in the network**

**Entities that carry out healthcare activity in the network**

**Article 28**

(1) The healthcare activity in the network, which is provided and organized by the Republic of Macedonia, shall consist of public healthcare institutions and private healthcare institutions that perform healthcare activity on the basis of a license (hereinafter: the license holders), where the healthcare activity is performed under the same conditions and which are included in an integrated health information system in accordance with the regulations in the field of health records.

(2) The healthcare institutions referred to in paragraph (1) of this Article shall be obliged to provide continuous and overall performance of the healthcare activity in the network at primary level by concluding mutual agreements.

(3) The agreements referred to in paragraph (2) of this Article shall regulate the mutual rights and obligations of the healthcare institutions particularly with regard to the provision of continuous 24-hour health protection every day of the year, the emergency medical care, as well as performance of healthcare activity during a state of crisis and emergency.

**Healthcare activity and parts of the healthcare activity performed solely within the network**
Article 29

(1) The healthcare activity and parts of the healthcare activity which are performed only in the network, unless otherwise envisaged by a law, shall be the following:
1) healthcare activity at tertiary level;
2) activity for supply of blood and blood components;
3) biomedical assisted insemination procedures;
4) procedures for harvesting and storing gametes;
5) activity for harvesting and transplanting human body parts for treatment purposes;
6) activity for emergent medical and dental medical care and in-house treatment;
7) examination of deceased persons;
8) health services concerning safety and health at work;
9) health services concerning safety in traffic;
10) health services related to determination of the mental ability to hold and carry weapons, in accordance with special regulations;
11) forensic medicine activity;
12) pathoanatomical medicine;
13) healthcare activity in the public health sector;
14) preventive health protection for pre-school and school children;
15) polyvalent district nursing;
16) health services to establish the health condition as part of the procedures for exercising the rights under the pension, disability and health insurance;
17) hospital care activities; and
18) dental medical protection for children up to the age of 14.

(2) The activities referred to in paragraph (1) points 1, 2, 4, 5, 6, 10, 11, 13, 14, 15 and 16 of this Article may only be performed by the public healthcare institutions, unless otherwise envisaged by law.

Healthcare activity at primary level

Article 30

(1) Healthcare activity at primary level shall include:
1) detection and treatment of diseases and injuries, provision of healthcare and obstetrics care, and provision of medical rehabilitation of patients that, in accordance with the distribution in the work, is part of the primary level;
2) implementation of special programs for chronically ill and elderly people;
3) healthcare activity in the field of sexual and reproductive health;
4) healthcare activity for the needs of the children and school youth;
5) healthcare activity in the field of safety and health at work;
6) implementation of preventive programs and measures for children, youth, women, employees and elderly people and other specially endangered groups, that is, groups that are specially exposed to particular health risks and implementation of screening programs for detection of the risk factors causing the disease, that is, for early detection of the first signs of the disease, except those screenings for which healthcare institutions at other levels are determined;
7) referral of patients to healthcare institutions at secondary and tertiary level and coordination of their treatment;
8) prevention, detection and treatment of mouth and teeth diseases and implementation of dental-prosthetic rehabilitation;
9) health treatment and medical rehabilitation of adults, children and youth with special needs;
10) district nursing activity;
11) immunization;
12) healthcare and obstetrics care;
13) treatment and in-house medical treatment of the patient;
14) emergency medical and dental medical care;
15) establishment of temporary absence from work and referral of the insured persons for expertise to
the social insurance funds;  
16) provision of medical laboratory services;  
17) prescription of medicaments; and  
18) pharmaceutical activity.

(2) The pharmaceutical activity referred to in paragraph (1) point 18 of this Article shall be performed in accordance with this Law and the regulations in the field of medicaments and medical devices.

Entities that carry out healthcare activity at primary level

Article 31

The healthcare activity referred to in Article 30 of this Law in the primary level network shall be performed at doctor’s offices and polyclinics, dental laboratories, health centers and pharmacies.

Chosen doctor

Article 32

(1) The patient shall choose a doctor within the primary level network (hereinafter: the chosen doctor).

(2) Chosen doctor shall be a doctor of medicine, specialist in general medicine, specialist in family medicine, specialist in school medicine, specialist in labor medicine in cases of carrying out activities of a family, that is, general practitioner, specialist in pediatrics, specialist in gynecology and obstetrics, and doctor of dental medicine.

(3) The chosen doctor shall particularly perform the following activities:
- treat patients in accordance with their health condition and with the expert instructions, providing an outpatient healthcare treatment and in-house treatment,
- provide preventive services and implement measures and activities determined by programs for promotion and maintenance of patients’ health,
- prescribe medicaments in accordance with the regulations in the field of mandatory health insurance,
- participate in the implementation of team forms of primary health protection activities, in the provision of emergency medical care and substitutions in case of illness and leave, medical examinations, advising and other types of health services for the purpose of determining, checking and monitoring the health condition, that as a rule is carried out in the office of the chosen doctor, and if necessary in the patient’s home,
- preventive measures and activities for the purpose of improving the health condition, preventing, eliminating and detecting early diseases and other health deteriorations,
- establish the justifiability of the temporary disability to work due to illness, injuries, accompaniment or isolation and absence from work due to pregnancy, childbirth and maternity (parenthood),
- establish the need of transport with ambulance vehicle in emergency cases, organize transport by an ambulance vehicle (independently, in cooperation with other doctors or with the nearest organized service for emergency medical care) and assess the justifiability for accompanying the patient,
- refer patients to the Fund in accordance with the regulations in the field of mandatory health insurance,
- refer patients to the Fund for Pension and Disability Insurance of Macedonia in accordance with the regulations in the field of pension and disability insurance,
- monitor the health treatment of the patient provided by specialists,
- collect, keep and store the medical documentation of the patient in accordance with the regulations in the field of health records, and
- carry out other activities in accordance with the regulations in the field of mandatory health insurance.
The procedure for choosing and the manner of working of the chosen doctor and the doctor substituting the chosen doctor and his/her tasks shall be done in accordance with this Law and the regulations in the field of mandatory health insurance.

**Article 32-a**

(1) The patient who cannot exercise the right to health protection at primary level in the place of residence shall have the right to health protection at primary level in a health center that carries out a healthcare activity at primary level and that have its head office in the area which covers the municipality of patient's place of residence.

(2) The right referred to in paragraph (1) of this Article shall not exclude the right of the patient to choose a doctor within the network at primary level in accordance with Article 32 paragraph (1) of this Law.

(3) The health protection referred to in paragraph (1) of this Article shall cover the activities set out in Article 32 paragraph (3) of this Law.

(4) The health protection referred to in paragraph (1) of this Article shall be provided by a doctor of medicine, a specialist in general medicine or a specialist in family medicine employed in the health center who are issued an approval for making and use of a seal in the course of provision of health protection at primary level by a competent body in accordance with the regulations on health insurance.

(5) The health center referred to in paragraph (1) of this Article shall be obliged to organize the healthcare activity at primary level referred to in paragraph (1) of this Article in populated places outside its head office in a manner which enables, as much as possible, the healthcare activity to be brought closer to the population, for which it shall adopt a program for carrying out the healthcare activity at primary level in populated places, previously consented by the Ministry of Health.

**Healthcare activity at secondary level**

**Article 33**

(1) The healthcare activity at secondary level shall include health services and measures which due to the severity of the illness, the need of expert specialized diagnostics and treatment, professional and technological complexity and multidisciplinary approach, that is, the necessity of hospital health treatment cannot be provided at primary level.

(2) The healthcare activity at secondary level shall include specialist and consultative and hospital healthcare activity.

**Contents of the specialist and consultative healthcare activity at secondary level**

**Article 34**

Specialist and consultative healthcare activity at secondary level shall include:
- outpatient examinations with a referral from the chosen doctor or another doctor specialist,
- healthcare treatments provided at secondary level, and
- day hospital activity.

**Contents of the hospital healthcare activity**
Article 35

(1) The hospital healthcare activity shall include diagnostics, treatment, health care and obstetrics care, medical rehabilitation and palliative care which, due to the health condition of the patient or the type of intervention, cannot be provided as specialist and consultative healthcare activity at secondary level or as in-house treatment.

(2) The hospital healthcare activity for a particular patient shall be provided as long as the health treatment cannot be continued in a specialist and consultative health activity at secondary level, that is, primary level, at home or in another institution.

(3) The hospital healthcare activity, in accordance with the network and the professional standards, shall be provided continuously and by ensuring complete healthcare treatment of patients.

Entities that carry out healthcare activity in the network at secondary level

Article 36

(1) The healthcare activity in the secondary level network shall be performed in doctor’s offices and polyclinics carrying out specialist and consultative healthcare activity, diagnostic laboratory, centers, hospitals, institutions and healthcare hospitals.

(2) As an exception to paragraph (1) of this Article, specialist and consultative healthcare activity for the area of two or more municipalities, that is, for the City of Skopje may be provided by a medical center as well, provided that it meets the requirements for such activities.

Healthcare activity at tertiary level

Article 37

The healthcare activity at tertiary level shall include:
- provision of health services that require expert, organizational and technologically complex and multidisciplinary healthcare treatment,
- complete and comparative monitoring of the development of particular specialties in the country and in other countries and preparation of national proposals for development of particular specialties,
- preparation of professional instructions and national proposals for development of particular type of healthcare activity, that is, health specialty and cooperation in their implementation,
- transfer of knowledge and skills from other countries,
- research and testing of new methods for prevention, detection, treatment, health and obstetrics care, and medical rehabilitation of health conditions, and
- advising and assistance regarding expert and medical issues of healthcare institutions at secondary and primary level, the Ministry of Health, the chambers and the Fund.

Entities that carry out healthcare activity at tertiary level

Article 38

(1) The healthcare activity at tertiary level shall be carried out by the university clinic, the university institute and the university clinical center.

(2) Particular healthcare activities, in accordance with the distribution of the performance of healthcare activity, may also be performed in institutions that perform scientific, research, and educational activity.
(3) As an exception, higher education activity in the field of medicine and dental medicine may also be carried out in clinical hospitals determined by an act of the ministry responsible for the issues in the field of higher education, upon previous consent of the Ministry of Health.

List of scheduled examinations and interventions

Article 39

(1) The schedule for using specialist, consultative, and hospital health services in the network at secondary and tertiary level of health protection, as well as the waiting period for their use, shall be carried out according to:
- the delivery of health service depending on the health condition of the patient and the assessment of the further course of the treatment that the chosen doctor has elaborated in the referral, that is, according to the assessment of the doctor specialist in the particular field of specialty in the healthcare institution where the health service is to be used, and in accordance with the priorities based on the evidence-based medicine,
- the type of health service,
- the time of registration of the patient for use of the health service, and
- the available capacity with regard to space, equipment and personnel for rendering the health service.

(2) The schedule for using the services referred to in paragraph (1) of this Article, within the framework of the type and scope of health services established in the agreement of the healthcare institution with the Fund, shall be kept by the healthcare institution on a web application administered by the Ministry of Health as an electronic list of scheduled examinations and interventions for using health services (hereinafter: the electronic list of scheduled examinations and interventions) in accordance with the criteria determined by this Law.

(3) The contents of the data kept in the electronic list of scheduled examinations and interventions and the manner of its keeping shall be prescribed by the minister of health.

(4) The healthcare institution shall be obliged to keep the electronic list of scheduled examinations and interventions in a form of a web application administered by the Ministry of Health and to publish it on a daily basis in a visible place in the premises of the institution especially determined for that particular purpose, as well as to update it every day no later than 15.00 o’clock.

(5) The healthcare institution shall be obliged to appoint at least two persons who shall keep, publish and update the electronic list of scheduled examinations and interventions.

(6) The personal data of the patient contained in the electronic list of scheduled examinations and interventions shall be published as coded data, which the patient receives at the moment of applying for using the health service.

Referral of patients

Article 39-a

(1) The chosen doctor shall be obliged to refer the patients to secondary and tertiary level of health protection to be rendered specialist and consultative services via the electronic list of scheduled examinations and interventions.

(2) The medical director of the healthcare institution in the network of secondary and tertiary level of health protection shall be obliged to establish in advance a calendar of free terms for specialist and consultative services no later than the tenth day of the current month for the following month for each worker who renders specialist and consultative services in the healthcare institution.
(3) For the purpose of providing the calendar referred to in paragraph (2) of this Article, the healthcare workers who provide specialist and consultative services in the healthcare institutions referred to in paragraph (2) of this Article shall be obliged to establish in advance a calendar of free terms for specialist and consultative services no later than the fifth day of the current month for the following month and to submit it to the director of the healthcare institution.

(4) The number of established free terms in the course of the month must not be below the average number of provided specialist and consultative services for the particular month in the preceding two years by the healthcare worker who renders specialist and consultative services in the healthcare institution referred to in paragraph (2) of this Article, that is, below the average number of provided specialist and consultative services for the entire period during which the healthcare worker has provided specialist and consultative services, if the period is shorter than two years.

(5) The healthcare worker who performs surgical interventions in the healthcare institutions referred to in paragraph (2) of this Article shall him/herself determine the term for the surgical intervention in agreement with the patient.

(6) The medical director of the healthcare institution referred to in paragraph (2) of this Article shall determine the duration of each surgical intervention both without and with complications on the basis of internationally accepted standards, that is, standards of professional medical associations.

(7) The patients shall be obliged to observe the term scheduled via the electronic list of scheduled examinations and interventions.

(8) If the patient is late for the term scheduled via the electronic list of scheduled examinations and interventions in the course of the day, he/she may be admitted upon the completion of all the other scheduled terms at the end of the working day.

(9) If the patient fails to appear at the term scheduled via the electronic list of scheduled examinations and interventions on the day it has been scheduled, he/she may reschedule the term via his/her selected doctor.

(10) If the duly scheduled term cannot be kept from whatever reason related to the healthcare institution, and the patient has not been notified thereof via phone or SMS at least three hours prior to the scheduled term, the travel costs incurred by the patient because the scheduled term has not been kept shall be covered by the healthcare institution in the network of secondary and tertiary level of health protection where the term has been scheduled in the amount of a bus ticket, upon a request submitted by the patient to the director of the healthcare institution.

(11) The director of the healthcare institution shall compensate the travel costs referred to in paragraph (10) of this Article within a day as of the submission of the request of the patient referred to in paragraph (10) of this Article and at the same time he/she shall be obliged to demand the employee in the healthcare institution because of whom the scheduled term has not been kept or due to whom the patient has not been informed within the time period referred to in paragraph (10) of this Article to compensate the costs referred to in paragraph (10) of this Article.

(12) For the purpose of unobstructed functioning of the electronic list of scheduled examinations and interventions, the directors of the healthcare institutions in the network of secondary and tertiary level of health protection shall be obliged to provide the healthcare institutions with permanent internet connection with availability of 99.9%, via a symmetrical connection which shall be used solely for communication with the Ministry of Health and the Fund.

(13) For the purpose of unobstructed functioning of the electronic list of scheduled examinations and interventions, the directors of the healthcare institutions where the selected doctors work shall be obliged to provide the healthcare institutions with permanent internet connection with availability of
99.9%, via an asymmetrical connection which shall be used solely for communication with the Ministry of Health and the Fund.

(14) The directors of the healthcare institutions in the network of secondary and tertiary level of health protection and the healthcare institutions where the selected doctors work, in addition to the internet connections referred to in paragraphs (13) and (14) of this Article, shall also be obliged to provide a backup internet connection with availability of 99.9%, via an asymmetrical connection which shall be used solely for communication with the Ministry of Health and the Fund, via another operator or via the same operator but using a different manner of establishing the connection.

(15) The healthcare institutions shall conclude service-level agreements with the operators that provide the internet connection which shall in particular regulate the operator’s obligation in case of interruptions in the functioning of the internet connection referred to in paragraphs (12), (13), and (14) of this Article.

Reference center

Article 40

(1) The activity of the reference centers shall be carried out by the general and specialized hospitals, that is, their departments and other healthcare institutions at secondary and tertiary level which are specialized in treating particular health conditions or in particular types of healthcare activity, that is, specialty.

(2) The healthcare institutions referred to in paragraph (1) of this Article may be awarded, that is, revoked the title – reference center by the minister of health, on the basis of a multi-year experience and demonstrated results in the performance of the activity.

(3) The detailed criteria regarding the multi-year experience and demonstrated results in the performance of the activity and the manner of awarding and revoking the title – reference center shall be prescribed by the minister of health.

2. Cooperation of the healthcare institutions in the network

Cooperation of the primary level healthcare institutions with other entities

Article 41

(1) Aiming at efficient and quality healthcare treatment of patients, the primary level healthcare institutions shall be obliged to cooperate with healthcare institutions at secondary and tertiary level.

(2) For the purpose of carrying out an activity in the field of public health, the healthcare institutions shall cooperate with the public health institutions, the municipalities, that is, the City of Skopje, the educational institutions, the social protection institutions, the associations and foundations, and the employers.

Cooperation among healthcare institutions at secondary level in the network

Article 42

(1) The secondary level healthcare institutions, within the territory of operation of the hospital, shall, by an agreement, regulate the mutual cooperation in the provision of emergency medical care and on-
duty work, the provision of services in accordance with the distribution of the performance of healthcare activity and the use of joint diagnostic and other capacities, and the other forms of cooperation.

(2) If a particular secondary level healthcare institution cannot provide temporarily the sufficient number of employed healthcare workers in accordance with the criteria for establishment of the network, that is, the agreement with the Fund, or it cannot meet its obligations towards the Fund due to other reasons, it shall conclude an agreement with one of the secondary level healthcare institutions for temporary transfer of the performance of a particular activity under its program, that is, for joint performance of that particular part.

(3) The agreement referred to in paragraph (2) of this Article shall also regulate the payment of the healthcare workers and the services related to the transferred performance of a particular activity referred to in paragraph (2) of this Article, as well as the purpose of the funds paid for the completed work under the program of the healthcare institution.

(4) If the agreement referred to in paragraph (2) of this Article is not concluded, the Fund shall decide about the temporary transfer of that part of the program, but for a year at the most.

Cooperation of the healthcare institutions at secondary level with other institutions

Article 43

(1) When discharging a patient from the hospital, the secondary level healthcare institutions shall, if necessary, mutually cooperate with other institutions.

(2) The hospitals and the other secondary level healthcare institutions shall make possible for the chosen doctors in the healthcare activity at primary level in the territory of their operation to make a phone or other form of expert consultation for the complex expert matters, within a period of 24 hours at the latest.

3. Performance of a healthcare activity in the network for patients who cover the health services by their own funds

Requirements for performance of a healthcare activity for patients who cover the health services by their own funds

Article 44

(1) The healthcare institutions in the network may perform a healthcare activity for patients who cover the health services by their own funds if:
- they hold a license for performing that particular healthcare activity and if they are entered in the register of healthcare institutions,
- in the last 12 months they have completely met their obligation under the agreement with the Fund or, as an exception, with the consent of the Ministry of Health,
- it does not affect the scope and the quality of provision of the healthcare activity in the network and the extension of the waiting time for using a particular service, and
- they have staff, spatial and other capacities that exceed the criteria for establishment of the network and the requirements under the agreement with the Fund and when they are not required for the provision of health services under the mandatory health insurance, in accordance with the agreement with the Fund, as well as for ensuring on-duty work and readiness.
(2) The healthcare institutions referred to in paragraph (1) of this Article may provide health services that:
- are not included in the mandatory health insurance on the basis of the regulations in the field of mandatory health insurance,
- are included in the mandatory health insurance but are provided if the patient requests a different or higher standard than the one determined by the regulations in the field of mandatory health insurance,
- are provided on the basis of agreements with foreign partners or beneficiaries, and
- are provided for foreigners that cover the costs for treatment by themselves.

(3) The healthcare institution referred to in paragraph (1) of this Article shall be obliged to display in a visible place that it also performs a healthcare activity for patients who cover the services by their own funds, the type of health services it provides in a form of a healthcare activity covered by own funds, the time and place of their performance, the prices of the health services, and the list of healthcare workers who perform such activity.

(4) The healthcare institution in the network may also provide health services to patients who cover the services by their own funds during the working hours intended for performing a healthcare activity in the network regarding health services that:
- are included in the mandatory health insurance, but are performed with materials chosen by the patient, of different or higher standard than the one determined by the regulations in the field of mandatory health insurance,
- are not included in the mandatory health insurance, but which cannot be provided separately from the health services included in the mandatory health insurance, upon previous consent from the Fund.

(5) The healthcare institution referred to in paragraph (1) of this Article shall be obliged, every six months, to submit a report to the Ministry of Health on the scope and type of health services provided for patients who cover the services by their own funds.

Records of the health services and purpose of the funds

Article 45

(1) The healthcare institutions in the network shall be obliged to keep separate records of the health services provided to patients who cover the services by their own funds.

(2) The surplus of the income over the expenditures which the public healthcare institutions in the network gain by carrying out the healthcare activity referred to in paragraph (1) of this Article shall be intended for development of the health services and the healthcare activity.

4. Performance of healthcare activity outside the network

Article 46

(1) The healthcare activity referred to in Article 26 paragraph (1) of this Law, except the activities referred to in Article 29 paragraph (1) of this Law, shall be provided outside the network by private healthcare institutions that meet the requirements referred to in Article 60 of this Law.

(2) The healthcare institutions outside the network shall carry out a healthcare activity by means of which they gain funds solely from patients who cover the health services by their own funds.

5. Setting up prices for health services in the public healthcare institutions

Article 47
(1) The prices of the health services in the public healthcare institutions for patients who cover the services with their own funds shall be set by the minister of health, on a request of the public healthcare institution, by a special act, and upon a previously obtained opinion from the Fund, having into consideration the costs for the service of the healthcare workers, that is, the teams that provided the service (labor), the costs for the ongoing and investment maintenance, the general operational costs (overheads), the medicaments and medical consumables, and other materials necessary for provision of the service.

(2) The minister of health may request an opinion from the competent chamber in the course of setting the price referred to in paragraph (1) of this Article.

(3) The public healthcare institutions referred to in paragraph (1) of this Article shall be obliged to issue a fiscal receipt for the health services provided to those patients who cover the services by their own funds.

6. Special areas of healthcare activity

Healthcare activity in the field of public health

Article 48

(1) The healthcare activity in the field of public health, that includes measures and activities for monitoring the health condition of the population, studying the risk factors, planning measures and activities for prevention of outbreak, early detection and prevention of disease spreading, measures for maintenance and promotion of health and environment, shall be performed in accordance with this Law and the regulations in the field of public health.

(2) The activity referred to in paragraph (1) of this Article shall be carried out by the public health centers and the Institute for Public Health of the Republic of Macedonia that plan and harmonize the carrying out of the tasks in the field of public health and cooperate with other healthcare institutions at all levels.

Activity in the field of safety and health at work, safety in the traffic, and determination of the health condition for possession and carrying of weapons

Article 49

The healthcare activity in the field of safety and health at work, safety in the traffic and determination of the health condition for possession and carrying of weapons shall be carried out in accordance with this Law and the special regulations in the corresponding fields.

Activity for blood supply and supply of blood components

Article 50

The activity of blood supply and supply of blood components shall be performed in accordance with this Law and the special regulations in the corresponding field.

Harvesting and transplanting human body parts and ensuring the quality and safety of the human tissues and cells

Article 51
The harvesting and the transplantation of human body parts and the ensuring of the quality and safety of the human tissues and cells intended for treatment shall be performed in accordance with this Law and the special regulations in the corresponding field.

**Procedures for treating infertility and biomedical assisted insemination procedures**

**Article 52**

The procedures for treating infertility and biomedical assisted insemination procedures shall be performed in accordance with this Law and the special regulations in the corresponding field.

**Emergency medical care activity**

**Article 53**

(1) The activity of emergency medical care shall include provision of diagnostic and therapeutic procedures which are necessary for elimination of a direct threat upon the person’s life and health.

(2) The emergency medical care activity shall be carried out at all levels of health protection, and shall be provided in the closest healthcare institution that has organized a service for emergency medical care, in accordance with the place of residence, that is, in the location of the person in need of emergency medical care.

(3) The organization and the manner of performance of the emergency medical care activities shall be determined by the minister of health.

**Examination of deceased persons**

**Article 54**

The examination of the deceased and the determination of the time and the causes of death shall be made in accordance with this Law.

**Funds for pension and disability insurance and health insurance**

**Article 55**

The Fund for Pension and Disability Insurance of Macedonia and the Fund shall, via commissions established in accordance with the regulations in the fields of pension and disability insurance and health insurance, carry out particular activities under the healthcare activity in the part that refers to assessing the working ability and exercising the rights deriving from these fields in accordance with the referred regulations.

**Health protection organized in accordance with the regulations in the field of defense**

**Article 56**

(1) The health protection organized in accordance with the regulations in the field of defense shall be performed in accordance with the regulations in the field of defense and the provisions of this Law that refer to the performance of healthcare activity.
(2) The healthcare activity referred to in paragraph (1) of this Article shall be performed on the basis of the license referred to in Article 62 of this Law.

IV. HEALTHCARE INSTITUTIONS

Establishment, status changes and licenses for work of the healthcare institutions

Establishment of healthcare institutions

Article 57

(1) The healthcare institution may be established as public and private.

(2) Public healthcare institution may be established by the Government.

(3) Private healthcare institution may be established by domestic and foreign legal entities and natural persons.

Establishment and status changes of public healthcare institutions

Article 58

(1) Public healthcare institution may be established and may terminate its activity by a decision of the Government, in accordance with the needs of the healthcare activity determined by the network.

(2) A decision on status changes (merging, acquisition, division, or separation) of the institutions referred to in paragraph (1) of this Article shall be adopted by the Government in accordance with the network established by this Law.

(3) On the basis of the decision referred to in paragraphs (1) and (2) of this Article, the public healthcare institution shall be registered, that is, the status changes shall be entered in the Central Register of the Republic of Macedonia.

Activities for which a private healthcare institution cannot be established

Article 59

Private healthcare institution cannot be established for carrying out the activities referred to in Article 29 paragraph (1) points 1, 2, 4, 5, 6, 10, 11, 13, 14, 15 and 16 of this Law, unless otherwise provided for by law.

Requirements for establishment, commencement of operation, performance of healthcare activity and expansion of the activity of the healthcare institution

Article 60

(1) A healthcare institution may be established, may commence its operation, may perform a healthcare activity and may expand the activity if the following requirements are met:
- to have employed a particular number of full time healthcare workers for an indefinite period of time, depending on the type of healthcare activity, that is, specialty,
- to have employed for an indefinite period of time a full time responsible holder of healthcare activity
to provide a certain type of health services depending on the type of healthcare activity, that is, specialty,
and
- to have space and equipment for performance of a particular type of healthcare activity, that is, specialty.

(2) The healthcare workers referred to in paragraph (1) lines 1 and 2 of this Article must hold an appropriate license for work, depending on the type of healthcare activity, that is, specialty.

(3) The responsible holder of the activity referred to in paragraph (1) line 2 of this Article must meet the following requirements:
- not to be a pension beneficiary and
- to be entered in the register of healthcare workers.

(4) A healthcare institution in the network, in addition to the requirements referred to in paragraph (1) of this Article, may be established, may commence its operation, may perform a healthcare activity, and may expand the activity if so planned by the network.

(5) The space, equipment and expert personnel necessary for establishment, commencement of operation, and performance of a healthcare activity in healthcare institutions shall be prescribed by the minister of health.

Contents of the study on establishment of a healthcare institution

Article 61

(1) The founder of the private healthcare institution outside the network shall, in the study on establishment of the institution, determine the type and scope of the healthcare activity, the space, equipment, required number of expert personnel including a list of people planned to be engaged, with data on their expert qualifications and a list of healthcare institutions where they have been previously employed or are employed, the amount of the funds and the manner of ensuring a sustainable level of financing of the activity for a period of six months, safety of the employees at work, safety of the beneficiaries of the public service, and it shall also attach a quality financial guarantee from a liquid bank or a mortgage of immovable property, acceptable for the Ministry of Health, intended for continuous provision of the services for a period of six months at the least and for compensation of the damage which might be inflicted on the beneficiaries of the services if the institution stops operating.

(2) The private healthcare institution shall be obliged to notify the Ministry of Health and the beneficiaries of health services about the termination of its operation at least six months in advance.

(3) The notification referred to in paragraph (2) of this Article shall be published on the web site of the Ministry of Health.

Decision on establishment and decision on license for work of the healthcare institution

Article 62

(1) The Ministry of Health shall assess the meeting of the requirements with regard to the space and/or the equipment referred to in Article 60 of this Law for establishment of a healthcare institution and it shall adopt a decision on establishment of a healthcare institution in the network, or a decision on establishment of a healthcare institution outside the healthcare institution network within a period of 60 days as of the day of receipt of the request.
(2) The healthcare institution shall be entered in the Central Register of the Republic of Macedonia on the basis of the decision referred to in paragraph (1) of this Article.

(3) A decision on license for work of the healthcare institution (hereinafter: the license for work) shall be adopted upon the fulfillment of the requirements with regard to the space, equipment and expert personnel referred to in Article 60 of this Law within a period of 30 days as of the day of receipt of the request, taking into consideration the employment of the expert personnel in the healthcare institution not to disturb the performance of the healthcare activity in the healthcare institution in the network wherefrom the expert personnel comes.

(4) The license for work shall be revoked in case of changes which cause divergence from the requirements determined in the decision referred to in paragraph (3) of this Article.

(5) The costs for the procedure referred to in paragraphs (1) and (3) of this Article shall be covered by the founder.

(6) The amount of the costs referred to in paragraph (5) of this Article on the basis of the material costs for conducting the procedure, and depending on the type of healthcare institution, shall be determined by the minister of health.

(7) If the Ministry of Health does not adopt a decision on the license for work, that is, it does not adopt a decision rejecting the request within the period referred to in paragraph (3) of this Article, the requesting entity shall have the right, within a period of three working days, to file a request to the filing office of the minister of health for him/her to adopt a decision.

(8) The form and the contents of the request referred to in paragraph (7) of this Article shall be prescribed by the minister of health.

(9) In addition to the request referred to in paragraph (7) of this Article, the requesting entity shall also submit a copy of the request referred to in paragraph (3) of this Article.

(10) The minister of health shall be obliged, within a period of five working days as of the day of submission of the request referred to in paragraph (7) of this Article to the filing office of the minister of health, to adopt a decision accepting or rejecting the request referred to in paragraph (3) of this Article. If the minister of health does not have a filing office, the request shall be submitted to the filing office of the Ministry of Health.

(11) If the minister of health does not adopt a decision within the period referred to in paragraph (10) of this Article, the requesting entity may notify the State Administrative Inspectorate within a period of five working days.

(12) The State Administrative Inspectorate shall be obliged, within a period of ten days as of the day of receipt of the notification referred to in paragraph (11) of this Article, to conduct supervision within the Ministry of Health to determine whether the procedure has been conducted in accordance with law and it shall notify the requesting entity of the measures taken within a period of three working days as of the day of the completed supervision.

(13) The inspector of the State Administrative Inspectorate shall, upon the completed supervision in accordance with the law, adopt a decision obliging the minister of health, within a period of ten days, to decide upon the submitted request, that is, to approve or reject the request and to notify the inspector about the adopted act. A copy of the act deciding upon the submitted request shall be attached to the notification.

(14) If the minister of health does not decide within the period referred to in paragraph (13) of this Article, the inspector shall file a motion for initiation of a misdemeanor procedure for a misdemeanor
determined by the Law on Administrative Inspection and shall set an additional period of five working days for the minister of health to decide upon the submitted request and shall notify the inspector about the adopted act within the same period. A copy of the act deciding upon the submitted request shall be attached to the notification. The inspector shall, within a period of three working days, inform the requesting entity of the measures taken.

(15) If the minister of health does not decide even in the additional time period referred to in paragraph (14) of this Article, the inspector shall file a report to the competent public prosecutor within a period of three working days and he/she shall inform the requesting entity about the measures taken within the same period.

(16) If the inspector does not act upon the notification referred to in paragraph (11) of this Article, the requesting entity shall have the right to file a complaint to the filing office of the director of the State Administrative Inspectorate within a period of five working days. If the director does not have a filing office, the request shall be submitted to the filing office in the head office of the State Administrative Inspectorate.

(17) The director of the State Administrative Inspectorate shall be obliged, within a period of three working days, to review the complaint referred to in paragraph (16) of this Article and if he/she establishes that the inspector has not acted upon the notification of the requesting entity in accordance with paragraph (11) and/or does not submit a report in accordance with paragraph (15) of this Article, the director of the State Administrative Inspectorate shall file a motion for initiation of a misdemeanor procedure for a misdemeanor determined by the Law on Administrative Inspection for the inspector and he/she shall set an additional period of five working days for the inspector to conduct supervision in the Ministry of Health whether the procedure has been conducted in accordance with law and shall, within a period of three working days as of the completed supervision, inform the requesting entity of the measures taken.

(18) If the inspector does not act even in the additional period referred to in paragraph (17) of this Article, the director of the State Administrative Inspectorate shall submit a report to the competent public prosecutor against the inspector and he/she shall inform the requesting entity about the measures taken within a period of three working days.

(19) In the case referred to in paragraph (18) of this Article the director of the State Administrative Inspectorate shall immediately, and within a period of one working day at the latest, authorize another inspector to immediately conduct the supervision.

(20) In the cases referred to in paragraph (19) of this Article, the director of the State Administrative Inspectorate shall inform the requesting entity about the measures taken within a period of three working days.

(21) If the director of the State Administrative Inspectorate does not act in accordance with paragraph (17) of this Article, the requesting entity may file a report to the competent public prosecutor within a period of eight working days.

(22) If the minister of health does not decide within the period referred to in paragraph (14) of this Article, the requesting entity may initiate an administrative dispute with the competent court.

(23) The procedure with the Administrative Court shall be urgent.

(24) Upon the adoption of the bylaw it shall be published on the web site of the Ministry of Health immediately or within a period of 24 hours at the latest.

(25) An appeal may be filed against the decision of the Ministry of Health rejecting the request for issuance of a license for commencement of operation within a period of eight days as of the day of
Contents of the license for work of the healthcare institution

Article 63

(1) The healthcare institutions shall be obliged to hold a license for work in order to perform a healthcare activity.

(2) The license for work of the healthcare institution shall contain the following data:
- name and head office of the healthcare institution,
- name and surname, that is, name of the founder, personal identification number and address, that is, head office,
- type of the healthcare institution,
- responsible holder of the healthcare activity and the other healthcare workers (personal name and surname, title, address of the permanent or temporary place of residence),
- type and manner of performance of the healthcare activity in the network or type and manner of performance of the healthcare activity outside the network, and
- list of health services that, in accordance with the requirements that are fulfilled, may be provided by the healthcare institution, based on the lists referred to in Article 26 paragraph (3) of this Law.

(3) In case of a change in the data referred to in paragraph (2) of this Article, upon a request of the healthcare institutions, the license for work shall be changed on the basis of the documentation that proves the change.

(4) The name of the healthcare institution must not contain terms and/or words referring to type and activity of a healthcare institution which are different from the type and activity of the institution which is established.

Entry of the healthcare institution in the register of healthcare institutions

Article 64

Upon the adoption of the license for work, the Ministry of Health shall ex officio enter the healthcare institution in the register of healthcare institutions.

Termination of operation and revocation of the license for work of the healthcare institution

Article 65

(1) The Ministry of Health shall adopt a decision on termination of operation of the healthcare institution if:
- the founder, that is, its legal, that is, lawful successor adopts an act on termination of the healthcare institution,
- the conditions for provision of the healthcare activity for which the healthcare institution has been founded have terminated,
- the healthcare institution is merged with, or acquired by, another healthcare institution or it is divided, or one or several institutions are separated in the case of which the newly established healthcare institutions, that is, the healthcare institutions merging with the healthcare institutions whose work has terminated, shall assume all the rights and obligations of the healthcare institutions the work of which terminates,
- it does not commence with the activity within a period of six months as of the entry in the register of
healthcare institutions or if it terminates the work for a period longer than one year, and
- the other conditions for termination of the healthcare institution determined by law or the articles of
incorporation are met.

(2) The Ministry of Health shall adopt a decision on revocation of the license for work of the healthcare
institutions if:
- within the determined time period, which cannot be shorter than 45 or longer than 60 days
  depending on the time necessary to eliminate the irregularities, it does not remove the irregularities
  established by the supervision in accordance with this Law,
- it does not notify the Ministry of Health of the changes in the data that are entered in the register of
  healthcare institutions within a period of 15 days after their occurrence,
- on the basis of a legally valid decision, nullity of the entry of the healthcare institution in the Central
  Register of the Republic of Macedonia is established,
- a sanction prohibiting the performance of the activity has been imposed due to failure to meet the
  requirements for the performance of the activity,
- it carries out an activity contrary to the license for work, and
- it does not implement the provisions of this Law and the acts adopted on the basis of this Law.

(3) As of the day of adoption of the decision referred to in paragraph (2) of this Article, the healthcare
institution shall terminate its operation.

(4) The consequences deriving from the decision revoking the license shall be borne by the founder.

(5) Pursuant to the decisions referred to in paragraphs (1) and (2) of this Article, the healthcare
institution shall be deleted from the Central Register of the Republic of Macedonia and from the
register of healthcare institutions.

(6) As an exception to paragraph (5) of this Article, the public healthcare institution shall be deleted
from the Central Register of the Republic of Macedonia on the basis of the founder's decision.

**Application of the regulations in the field of general administrative procedure**

**Article 66**

The regulations in the field of general administrative procedure shall apply to the procedures for
establishment, status changes (merging, acquisition, division or separation) and licenses for work of
healthcare institutions, unless otherwise determined by this Law.

**Register of healthcare institutions**

**Article 67**

(1) The register of healthcare institutions shall be public and shall contain the following data:
1) name and head office of the healthcare institution;
2) name and surname, that is, name of the founder;
3) healthcare institution type;
4) type and manner of provision of the healthcare activity in the network; and
5) type and manner of provision of the healthcare activity outside the network.

(2) The register of healthcare institutions shall be kept and published by the Ministry of Health on the
web site of the Ministry of Health.
(3) The Ministry of Health shall ensure access to the data from the register referred to in paragraph (1) of this Article for the Institute of Public Health of the Republic of Macedonia, in accordance with the regulations in the field of health records.

(4) The register of healthcare institutions shall be used by the competent inspections, the Fund and the chambers within the delegated public powers.

(5) The form, the contents, the manner of keeping and publishing the register referred to in paragraph (1) of this Article shall be prescribed by the minister of health.

7. Types of healthcare institutions

Determination of the types of healthcare institutions

Article 68

(1) Depending on the type of healthcare activity performed and the type of health services provided, the healthcare institutions shall be established as:
- doctor’s office,
- polyclinic,
- diagnostic laboratory,
- dental laboratory,
- center,
- medical center,
- hospital (general, specialized, clinical),
- care, care, care,
- institute, clinic, institute,
- university clinical center, and
- pharmacy.

(2) As an exception to paragraph (1) of this Article, for the purpose of more efficient and more rational use of the space, equipment and personnel in the public healthcare institutions, the Government, on a proposal of the minister of health, may reach a decision on merging, that is, acquisition of two or more public healthcare institutions of different type and/or level in one public healthcare institution with expanded activity where the healthcare activity shall be carried out and the health services of the public healthcare institutions which are to be merged or acquired shall be rendered, or on division or separation of one public healthcare institution in two or more types of public healthcare institutions where the healthcare activity shall be carried out and the health services of the public healthcare institutions which are to be divided or separated shall be rendered.

Doctor’s office

Article 69

(1) A doctor’s office at primary level shall perform a healthcare activity if the requirements for performance of an activity in a family, that is, general medicine, school medicine, pediatrics, labor medicine, gynecology and obstetrics and general dental medicine are met.

(2) A doctor’s office at secondary level shall perform specialist and consultative healthcare activity in the field of medicine, that is, dental medicine.

Polyclinic
Article 70

(1) A polyclinic at primary level shall carry out a healthcare activity in two or several doctor’s offices at primary level and an appropriate diagnostic and laboratory, that is, dental and laboratory activity, depending on the healthcare activity performed in the doctor’s offices.

(2) A polyclinic at secondary level shall carry out a healthcare activity of two or several doctor’s offices in the specialist and consultative activity and an appropriate diagnostic and laboratory, that is, dental and laboratory activity, and a radio diagnostic activity, depending on the healthcare activity performed in the doctor’s offices.

(3) The polyclinics referred to in paragraphs (1) and (2) of this Article may carry out a healthcare activity even if the appropriate diagnostic and laboratory, that is, dental and laboratory activity, and radio diagnostic activity is provided in agreement with another healthcare institution.

Diagnostic laboratory

Article 71

A diagnostic laboratory shall carry out an activity related to taking laboratory samples, processing and analyzing by using diagnostic equipment, apparatuses, and physical and diagnostic methods with a list of health services for the needs of the primary or specialist and consultative activity.

Dental laboratory

Article 72

A dental laboratory shall perform an activity related to preparation and manufacture of dental, technical and prosthodontic devices (prosthesis, bridges, crowns and alike).

Medical center

Article 73

(1) A medical center shall perform a healthcare activity at least in the following fields:
- emergency medical care and in-house treatment,
- emergency dental care,
- preventive health protection for pre-school and school children,
- polyvalent medical care for district nursing,
- dental protection for children younger than 14, and
- health statistics.

(2) The medical center shall perform the healthcare activity by applying dispensary and team work method.

(3) In the course of carrying out the healthcare activity referred to in paragraph (1) of this Article, the healthcare workers shall promote and direct the preventive activities and the activities for health promotion of patients and shall cooperate with healthcare workers in the specialist and consultative, and hospital health protection.

(4) The medical center may also perform other primary and/or specialist and consultative activities if it meets the requirements for those activities in accordance with this Law.
(5) The medical center may organize childbirth with expert assistance, provided that there is no general hospital on its territory.

**Center**

**Article 74**

(1) The center, for the territory for which it has been established, shall organize and implement measures in order to provide the patients with emergency medical care from the place where the emergency health condition occurs by taking measures for reanimation and intensive care to the place of the closest appropriate healthcare institution for admission and treatment, acute treatment, healing and treatment of the chronically ill, rehabilitation and reintegration, as well as other type of support.

(2) A center shall be established for emergency medical care, mental health, healing and treatment of the chronically ill, treatment of addictions, and rehabilitation.

(3) In addition to the activities referred to in paragraph (1) of this Article, the center for emergency medical care shall also be obliged to organize in-house treatment.

(4) A center shall also be established for performing the public health activities in accordance with the Law on Public Health.

**Hospital**

**Article 75**

(1) The hospital shall perform a hospital healthcare activity that includes diagnostics, treatment, health care and obstetrics care, medical rehabilitation and palliative care, which due to the health condition of the patient or the type of intervention, is impossible to be carried out as an outpatient healthcare activity at secondary level or treatment in the center, in the center for special care, that is, at home.

(2) The hospital may also carry out specialist and consultative healthcare activity at secondary level for those types of healthcare activity for which it performs hospital healthcare activity.

(3) The hospital may be general, specialized and clinical.

**General hospital**

**Article 76**

(1) The general hospital shall perform a hospital healthcare activity in the field of internal medicine, general surgery, gynecology and obstetrics, and child diseases.

(2) As an exception to paragraph (1) of this Article, provided that it is in accordance with the network at secondary level, the general hospital may perform a hospital healthcare activity only in the field of internal medicine and general surgery.

(3) The general hospital shall also provide intensive care and therapy, anesthesiology, emergency medical care, laboratory medicine, radio diagnostics and other activities within a scope necessary for performing a diagnostic activity, activity for special care and therapeutic activity within the limits of the hospital healthcare activity, palliative care, as well as provision of medicaments to the patients treated in the hospital.
In addition to the activities of a general hospital, the City General Hospital "8 Septemvri" in Skopje may also provide a healthcare activity for preventive, periodical and control health examinations of all persons, as well as check of the health status of specific categories of occupations of employees, civil and public servants, the status of whom is regulated by special regulations.

**Specialized hospital**

**Article 77**

(1) The specialized hospital shall perform a hospital healthcare activity and specialist and consultative healthcare activity for particular types of diseases or adult groups of the population.

(2) The specialized hospital, depending on the type of the healthcare activity, shall also provide intensive care and therapy, anesthesiology, emergency medical care, as well as laboratory medicine, radiology and other activities in the scope required for performing diagnostic activity, special care activity and therapeutic activity within the limits of the hospital healthcare activity and the specialist and consultative healthcare activity it performs, as well as provision of medicaments to the patients treated in the hospital.

**Clinical hospital**

**Article 78**

(1) The clinical hospital shall carry out a healthcare activity of a general hospital referred to in Article 76 paragraph (1) of this Law, as well as a healthcare activity in the field of urology, neurosurgery, orthopedics and traumatology, ocular diseases, otorhinolaryngology, neonatology, psychiatry, neurology and oncology.

(2) Educational activity and professional development of healthcare workers in the field of medicine, dental medicine and pharmacy and of healthcare co-workers shall be also conducted in the clinical hospital.

**Hospital for special care**

**Article 79**

(1) The hospital for special care shall provide health care for patients whose acute treatment of the disease or injury, for which they have been admitted to the hospital, is completed, but who, due to their general health condition, require health care that still cannot be provided at home or in another type of institution.

(2) The hospital for special care shall conclude an agreement with a general hospital with which it cooperates during health treatment of the chronically ill patients, in accordance with the instructions for evidence-based medicine.

(3) The hospital for special care may also provide palliative care and institutional protection of the chronically ill and the other patients who need assistance in the performance of their everyday activities, in accordance with the regulations in the field of social protection.

**Categorization of healthcare institutions that carry out a hospital healthcare activity in the network**

**Article 80**
(1) For the purpose of ensuring the minimum standard of professional development, rational administrative management, rational management of the space, equipment and personnel, and with the purpose of ensuring minimum standard of quality of the healthcare activity and equal development all over the territory of the Republic of Macedonia, the healthcare institutions that carry out a hospital healthcare activity in the network shall be divided in the following categories: zero, first, second and third.

(2) The categories referred to in paragraph (1) of this Article shall be determined depending on the type of healthcare activity and the number of activities, the level of professional training of the healthcare workers, the level of the health services, the scope of provision of health services, bed capacities and geographic area for provision of health services for the population.

(3) The detailed criteria referred to in paragraph (2) of this Article regarding the division into categories of the healthcare institutions carrying out a hospital healthcare activity in the network shall be prescribed by the minister of health.

Institute

Article 81

The institute shall carry out a healthcare activity if the requirements determined by this Law for a specialized hospital, as well as the requirements for performance of a scientific and research activity under this and another law, are met.

Institute of Transfusion Medicine

Article 82

The Institute of Transfusion Medicine of the Republic of Macedonia, in addition to the activities determined by the regulations in the field of safety of blood supply, shall also plan, promote and organize blood donation actions in the Republic, it shall collect, store and distribute blood for the needs of the healthcare institutions, it shall prepare test serums, produce blood derivatives and parenteral solutions, it shall carry out immunohematological, immunologic examinations of histocompatibility, chemostats, and it shall build up and implement expert and medical doctrinaire criteria in its field.

Institute of Labor Medicine

Article 83

The Institute of Labor Medicine of the Republic of Macedonia shall carry out a highly specialized healthcare activity in the field of labor medicine, specialist and consultative health services, shall carry out activities for promotion of the health at work, shall conduct ambient monitoring of the work environment and shall assess the job risks, shall create and implement expert and medical doctrinaire criteria in its field, shall develop and apply information system in the field of safety and health at work, shall deliver training to healthcare workers, shall provide expert and methodological assistance, and shall coordinate the healthcare institutions in the field of labor medicine, and shall perform scientific and research activity in the field of labor medicine.

Institute for Public Health

Article 84
The Institute for Public Health of the Republic of Macedonia shall perform the activities determined by the regulations in the field of public health.

**University clinic**

**Article 85**

(1) The university clinic shall carry out a healthcare activity if the requirements for provision of a specialist and consultative and hospital activity or only a specialist and consultative activity in a particular field of medicine, that is, dental medicine, or to particular groups of the population are met, where educational activity is carried out, where healthcare workers are professionally developed and a scientific and research activity is carried out.

(2) In addition to the activities referred to in paragraph (1) of this Article, the university clinic shall particularly provide health services that require expert, organizational, and technologically complex and multidisciplinary healthcare treatment of a particular branch of medicine, that is, dental medicine, it shall create and implement expert and medical doctrinaire criteria in its field, and it shall provide expert and methodological assistance to the healthcare institutions in the particular branch of medicine, that is, dental medicine.

(3) The university clinic may perform an activity if it has at least five doctors of medicine, that is, doctors of dental medicine employed, at least two of whom are professors at a faculty of medicine, that is, at a faculty of dental medicine.

(4) The university clinic may perform an activity even if the professors referred to in paragraph (3) of this Article are employed at the university clinic and at a faculty of medicine, that is, a faculty of dental medicine, in accordance with the regulations in the field of labor relations and the employment contract.

**University institute**

**Article 86**

(1) The university institute shall carry out a specialist and consultative health activity, educational and scientific and research activity, shall deliver professional development trainings to healthcare workers if it meets the requirements referred to in Article 85 paragraphs (3) and (4) of this Law.

(2) In addition to the activities referred to in paragraph (1) of this Article, the university institute shall particularly provide health services that require expert, organizational and technologically complex and multidisciplinary healthcare treatment of a particular branch of medicine, foremost in the field of complex diagnostic procedures, it shall create and implement expert and medical doctrinaire criteria in its field and it shall provide expert and medical assistance to healthcare institutions of a corresponding branch of the medicine.

**University clinical center**

**Article 87**

(1) A university clinical center shall be a healthcare institution that as a rule provides health services that require expert, organizational and technologically complex and multidisciplinary healthcare treatment from several branches of medicine, that is, dental medicine, and performs educational and scientific and research activity, ensures functional connection of the activities, organizes unified laboratory and diagnostic activity, x-ray diagnostic, anesthesiology and reanimation activity, admission and triage of the ill, provision of medicaments and sanitary materials.
(2) In addition to the activities referred to in paragraph (1) of this Article, the university clinical center shall also provide specialist and consultative and hospital health protection.

(3) In addition to the activities referred to in paragraphs (1) and (2) of this Article, in accordance with the nature of the activity and for the purpose of implementing the educational, scientific and research activity, the university clinical center in the field of dental medicine may also provide services within the primary dental health protection, on the basis of an approval of the minister of health.

Functional whole of the health, educational and scientific and research activity

Article 88

(1) The university clinic, the university institute, that is, the university clinical center and the clinical hospital shall perform the educational and scientific and research activity in a manner that ensures functional whole of the health, educational and scientific and research activity and in accordance with the needs of the faculty of medicine, that is, the faculty of dental medicine for implementation of the study programs.

(2) The university clinic, that is, the university clinical center, the clinical hospital, and the faculty of medicine, that is, the faculty of dental medicine shall regulate the mutual relations in the provision of the activities referred to in paragraph (1) of this Article, as well as the conditions and the manner according to which the entities referred to in Article 85 paragraph (4) of this Law perform health, that is, higher educational and scientific and research activity, by an agreement.

(3) In the performance of the health, educational, and scientific and research activity as a functional whole in the university clinic, university institute, university clinical center and clinical hospital the persons elected in educational, scientific and associate titles in a higher education institution shall perform a higher education activity, in accordance with the agreement referred to in paragraph (2) of this Article.

Pharmacy

Article 89

The pharmacy shall perform a pharmacy activity, and in particular procurement, storage, keeping, issuance, examination and control of medicaments, sanitary materials and medicinal substances, it shall produce magistral medicaments and preparations, it shall provide instructions for use of the issued medicaments, and it shall procure and issue products for child and diet nutrition, orthopedic devices, tools and medical instruments.

8. Joint provisions on healthcare institutions

General acts of healthcare institutions

Article 90

A healthcare institution, depending on the activity it performs, shall be obliged to regulate in particular the following matters by a general act: the organization and the manner of providing emergency medical care, the manner of using and maintaining the medical equipment, the care of the ill and in-house treatment, the manner and procedure for admission of patients when providing primary, specialist, consultative and hospital health protection, the manner and the contents of conducting internal supervision of the expert work of the healthcare workers and healthcare co-workers, and the type and the manner of using the working and protective clothing of the healthcare and other workers.
Internal organization of public healthcare institutions

Article 91

(1) The work in the public healthcare institutions, based on the principles of accessibility, rationality, efficiency and continuity of the health protection, shall be organized in internal organizational units, which constitute organizational and technical whole of the work process, depending on the type of healthcare institution.

(2) The following may be established as internal organizational units:
- service and depot for medicaments in a medical center,
- unit, department, division and hospital pharmacy within the hospital and institute,
- unit and hospital pharmacy within a university institute and university clinic, and
- clinic with units and hospital pharmacy within the university clinic center.

(3) Depending on the type of the activity performed by the healthcare institution, the scope of operation of the internal organizational units and the minimum number of persons performing the activities per internal organizational unit shall be prescribed by the minister of health, in accordance with the principles referred to in paragraph (1) of this Article.

Management of a unit in a university institute, a university clinics and a clinic in a university clinical center

Article 91-a

(1) A head of a unit shall manage the unit in a university institute, a university clinics and a clinic in a university clinical center and shall organize the work process in the unit and shall be accountable for the lawfulness and professionalism in the operation of the unit to the director, that is, the directors.

(2) A person who meets the following requirements may be a head of a unit referred to in paragraph (1) of this Article:
- to be a doctor of medicine, specialist or subspecialist, or a doctor of dental medicine, specialist or subspecialist, that is, a healthcare worker with a higher education in pharmacy with an appropriate specialization or subspecialization,
- to have at least seven years of work experience in the profession,
- to have active knowledge in one of the three most commonly used languages in the European Union (English, German or French) at B2 level according to the European language portfolio (Common European Framework of Reference for Languages: Learning, Teaching, Assessment) (hereinafter: CEFR) and to hold an internationally recognized certificate issued by an official European tester, a member of ALTE (Association of Language Testers in Europe) at B2 level of CEFR, that is, IELTS with 5-6 points, FCE, BEC, ILEC, ICFE, BULATS, or APTIS, or TOEFL PBT at least 500 points, TOEFL CBT at least 175 points or TOEFL IBT at least 60 points or DELF, TCF, TEF, or Goethe-Zertifikat, TestDaF,
- to have published at least one paper in a scientific journal having an impact factor or to be a holder or coordinator of a national, regional or international scientific and research project,
- to have introduced at least two new healthcare methods or procedures in at least two public healthcare institutions (in a public healthcare institution at tertiary level, in a clinic and/or a general hospital) in the Republic of Macedonia, and
- to have lived abroad for at least six months in total in the last five years for the purpose of professional development or participation in international events as a lecturer or educator.

(3) The level of a foreign language knowledge referred to in paragraph (2) line 3 of this Article shall be verified by attaching one of the following internationally recognized certificates or internationally used certificates: APTIS, BULATS, CAE, IELTS, FCE, BEC, PET, KET, ILEC, TOEFL PBT, TOEFL CBT, TOEFL IBT for the English language, that is, DELF, DALF, TCF, TEF, BULATS for the French language, that is, Goethe-Zertifikat, TestDaF and BULATS for the German language, or another internationally
recognized certificate issued by an official European tester, a member of ALTE (Association of Language Testers in Europe) or other international organizations, at B2 level of the Common European Framework of Reference for Languages (CEFR).

(4) The knowledge of a foreign language referred to in paragraph (2) line 3 of this Article, in addition to internationally recognized certificates or internationally used certificates, shall be verified by a certificate of a completed first, second or third cycle of studies at one of the top 200 universities under the Shanghai Ranking-ARWU (Academic Ranking of World Universities) in one of the three most commonly used languages of the European Union (English, French, German) for the studies of which the candidate holds a validated diploma.

(5) It shall be deemed that the candidate meets the requirement referred to in paragraph (2) line 5 of this Article if the public healthcare institution at tertiary level, the clinic and/or the general hospital uses the new healthcare method or procedure independently, without direct participation of the candidate.

(6) The head of the unit referred to in paragraph (1) of this Article shall be appointed for a period of six years with the right to be re-appointed upon the expiry of this period, based on a public announcement published by the governing board of the university institute, the university clinic or the clinic in the university clinical center, on a proposal of the director of the university institute, the university clinic or the clinic in the university clinical center.

(7) Upon expiry of the period referred to in paragraph (6) of this Article, the person shall be assigned in the university institute, the university clinic or the clinic in the university clinical center to a job appropriate to his/her education and experience.

Management and governance of private healthcare institutions

Article 92

The management and governance of private healthcare institutions shall be regulated by the articles of incorporation, that is, the statute of the institution.

Day hospital

Article 93

The hospital and the other healthcare institutions that carry out a specialist and consultative healthcare activity may also organize the performance of the healthcare activity by accommodating the ill only at a particular time during the day (day hospital).

Cooperation among healthcare institutions

Article 94

In order to ensure efficient, integrated and quality treatment of the patients, the healthcare institutions shall cooperate among themselves, in accordance with this Law.

Association of healthcare institutions

Article 95
The healthcare institutions may form an association of healthcare institutions for the purpose of regulating particular matters of joint interest.

V. OTHER LEGAL ENTITIES THAT PERFORM HEALTHCARE ACTIVITY

Article 96

(1) The institutions that carry out a scientific and research and educational activity in the field of medicine, dental medicine and pharmacy may perform a healthcare activity if they meet the requirements for performance of a particular healthcare activity.

(2) The institutions in the field of social protection, penitentiary institutions and educational and correctional institutions may implement particular measures under the healthcare activity at primary level only for the persons accommodated therein.

(3) The state bodies, judiciary bodies, as well as the trade companies with more than 100 employees shall mandatorily organize a healthcare point as an internal organizational unit.

(4) Hotels with capacity of more than 100 beds shall mandatorily organize a healthcare point as an internal organizational unit.

(5) The local self-government units shall mandatorily organize healthcare points with defibrillator and at least five trained people to use the defibrillator, in at least one location within the area of the local self-government unit.

(6) The location of the healthcare points referred to in paragraph (5) of this Article shall be determined by the minister of health.

(7) The healthcare points referred to in paragraphs (3), (4) and (5) of this Article shall provide medical care for people in life-threatening condition until they are urgently transferred to the appropriate healthcare institution and they shall meet the requirements in terms of space, equipment and personnel, prescribed by the minister of health.

(8) The healthcare services provided at the healthcare points shall not be covered by the Fund.

Article 97

The provisions of this Law pertaining to the commencement of operation of healthcare institutions, the healthcare workers and the healthcare co-workers, the health records, the supervision of the work of healthcare institutions shall also apply to the legal entities referred to in Article 96 of this Law.

VI. GOVERNANCE AND MANAGEMENT OF PUBLIC HEALTHCARE INSTITUTIONS

Meeting the public interest

Article 98

The public interest in the performance of healthcare activity in the public healthcare institutions shall be met by:
- participation of representatives of the founder in the decision-making on issues of public interest,
granting consent to the statutes, and 
appointment and dismissal of a director.

**Issues of public interest**

**Article 99**

Representatives of the founder of the public healthcare institutions shall take part in the decision making on the following matters of public interest:
- adoption of a statute,
- adoption of a decision on a change of activity or other status changes (merging, acquisition, division or separation),
- adoption of a work program and a financial plan,
- determination of an annual account, and
- adoption of a work report.

**Governing board**

**Article 100**

(1) The public healthcare institution shall be governed by a governing board.

(2) The governing board of the public healthcare institutions of specialist and consultative, and hospital health protection shall be composed of five members, two of whom shall be representatives from among the expert and competent persons in the public healthcare institution elected by the expert body, and three representatives of the founder.

(3) The governing board of the public healthcare institutions of primary health protection shall be composed of five members, three of whom shall be representatives of the founder and two representatives of the local self-government units, one of whom shall be appointed by the council of the municipality on the territory of which the head office of the public healthcare institution is located, and the other by the council of the municipality with the largest number of citizens on the territory covered by the healthcare institution, excluding the municipality on the territory of which the head office of the healthcare institution is located in case it has the largest number of citizens.

(4) As an exception to paragraph (3) of this Article, the two representatives of the local self-government units in the public healthcare institution providing primary health protection on the territory of the City of Skopje shall be appointed by the Council of the City of Skopje.

(5) The governing board shall adopt the statute of the institution, shall adopt a decision on a change of activity and on the other status changes (division, separation, merger and acquisition), shall adopt the work report, the work program and the financial plan, shall determine the annual account, shall adopt general acts and shall monitor their implementation, and shall also carry out other activities determined by law, the articles of incorporation and the statute of the public healthcare institution.

(6) The decision on a change of activity and the other status changes (division, separation, merger and acquisition) referred to in paragraph (5) of this Article shall be adopted by the governing board upon previous consent of the founder.

(7) The manner of election of the members of the governing board, the duration of the term of office, and the manner of decision-making shall be regulated by the statute of the public healthcare institution.

(8) The principle of equitable representation of all the communities in the Republic of Macedonia shall apply to the election of the members of the governing board.
Criteria for appointing a member of a governing board

Article 101

(1) A member of a governing board may be appointed a person who holds at least a university degree and has at least five years of work experience in the field of health, economy or law.

(2) A member of a governing board cannot be appointed a person who, besides the cases determined in the Law on Institutions, is:
- employed or holds stocks or shares in legal entities that manufacture, or trade in, medicaments, medical devices, that is, medical equipment,
- a close person to a member of the governing board, and
- in other cases determined by the regulations in the field of prevention of conflict of interests.

Dismissal and termination of the term of office of a governing board member

Article 102

(1) A member of a governing board of a public healthcare institution may be dismissed before the expiry of the term of office for which he/she is appointed if:
1) the basis on which he/she has been appointed is no longer valid;
2) he/she has not attended the sessions of the governing board without justification at least twice a year;
3) it is additionally confirmed that he/she is a person close to a member of the governing board, as well as in other cases determined by the regulations in the field of prevention of conflict of interests;
4) it is additionally confirmed that he/she has personal, through a third party, or on any other basis, interests that may in whatever manner affect his/her independence and impartiality;
5) he/she meets the obligations in the governing board in a negligent or inefficient manner; and
6) he/she works contrary to the provisions of this Law.

(2) The term of office of a member of a governing board of a public healthcare institution shall terminate before the expiry of the time for which he/she is appointed:
1) at his/her request and
2) in the case of a permanent or temporary inability for unobstructed performance of the function or in case of death.

Consent to the statute

Article 103

The Ministry of Health shall give its consent to the provisions of the statute of the public healthcare institution.

Management body

Article 104

(1) The management body of the public healthcare institution (hereinafter: the director) shall organize and manage the process of labor, shall manage the work of the public healthcare institution, shall independently adopt decisions within his/her competences, shall represent the public healthcare institution towards third parties, and it shall be responsible for the lawfulness of the operation of the public healthcare institution and for the obligations assumed in the legal transactions.
(2) A person who meets the following requirements may be appointed as a director:
1) to be a citizen of the Republic of Macedonia;
2) at the moment of appointment, not to be issued an effective injunction banning him/her from exercising a profession, business or office;
3) to have completed a higher education in the field of medical and dental sciences, a higher education - a graduated speech therapist, a higher education - specialist in medical biochemistry, a higher education in the field of economy and law or public health management, or completed academic studies with at least 240 ECTS, that is, at least VI B level under the National Framework for Higher Education Qualifications;
4) to have at least five years of work experience and a passed director examination in accordance with this Law;
5) to offer a work program for the public healthcare institution of the most quality;
6) to hold one of the following internationally recognized certificates for active knowledge of English Language which is not older than five years:
   - TOEFL IBT - at least 74 points,
   - IELTS - at least 6 points,
   - ILEC (Cambridge English: Legal) - at least B2 level,
   - FCE (Cambridge English: First) - passed
   - BULATS - at least 60 points, or
   - APTIS - at least B2 level; and
7) to have passed a psychological test and an integrity test.

(3) The rights and obligations between the director and the employer shall be regulated by a managerial contract that shall particularly contain indicators of success for the director to achieve.

(4) The managerial contract shall particularly contain provisions on contractual penalty for non-observance of the managerial contract by the director that shall be determined by the minister of health in the one-time amount of Euro 50 to 100 in Denar counter-value, or Euro 50 to 100 in Denar counter-value for a period of one to six months.

**Duty of a director performed by two persons**

**Article 105**

(1) As an exception to Article 104 of this Law, two directors shall be appointed in a public healthcare institution: medical center with more than 1.000 employees, university clinical center, university clinic, clinical hospital, university institute and institute, that is, an organizational director and a medical director who shall be responsible for the operation of the public healthcare institution and the obligations assumed in the legal transactions in accordance with the competences determined by this or another law, the bylaws and the managerial contract.

(2) A person who meets the following requirements may be appointed as a medical director:
1) to be a citizen of the Republic of Macedonia;
2) at the moment of appointment, not to be issued an effective injunction banning him/her from exercising a profession, business or office;
3) to have completed a higher education in the field of medical and dental sciences, a higher education - a graduated speech therapist, a higher education - specialist in medical biochemistry, or completed academic studies with at least 240 ECTS, that is, at least VI B level under the National Framework for Higher Education Qualifications;
4) to have at least five years of work experience in a healthcare institution and a passed director examination in accordance with this Law;
5) to hold one of the following internationally recognized certificates for active knowledge of English
Language which is not older than five years: 10
- TOEFL IBT - at least 74 points,
- IELTS - at least 6 points,
- ILEC (Cambridge English: Legal) - at least B2 level,
- FCE (Cambridge English: First) - passed
- BULATS - at least 60 points, or
- APTIS - at least B2 level; and

6) to have passed a psychological test and an integrity test.

(3) The medical director shall have sole competence and responsibility in particular for:
- organization of the work of the healthcare workers and healthcare co-workers,
- promotion of the diagnostic and therapeutic procedures and the quality of the health services,
- application of the professional instructions in evidence-based medicine, and
- economy in the provision of health services.

11

(4) A person who meets the following requirements may be appointed as an organizational director:
1) to be a citizen of the Republic of Macedonia;
2) at the moment of appointment, not to be issued an effective injunction banning him/her from exercising a profession, business or office;
3) to have completed a higher education in the field of economy or law or public health management, or completed academic studies with at least 240 ECTS, that is, at least VI B level under the National Framework for Higher Education Qualifications;
4) to have at least five years of work experience in the field of economy, finance, law or management, or of the system and organization of the health protection and health insurance and a passed director examination in accordance with this Law;
5) to hold one of the following internationally recognized certificates for active knowledge of English Language which is not older than five years: 12
- TOEFL IBT - at least 74 points,
- IELTS - at least 6 points,
- ILEC (Cambridge English: Legal) - at least B2 level,
- FCE (Cambridge English: First) - passed
- BULATS - at least 60 points, or
- APTIS - at least B2 level; and

6) to have passed a psychological test and an integrity test.

(5) The organizational director shall have sole competence and responsibility in particular for:
- the organization of the work concerning the work of the employees in the public healthcare institution who are not healthcare workers and healthcare co-workers,
- the control of the observance of the working hours by all the employees in the public healthcare institution,
- the material and financial operation of the public healthcare institution,
- the material accounting,
- the decision-making on the rights and obligations under employment of the employees in the public healthcare institutions,
- the supply of the public healthcare institution with consumables,
- the collection of the public healthcare institution own revenues, and
- the collection of the participation of the insured who pay the services with their own funds in the price of the health services in the public healthcare institution.

(6) The medical and the organizational director shall have joint competence and responsibility for everything that is not in the exclusive competence of the medical or the organizational director, and in particular for:
- preparation of a draft plan for public procurement and its submission to the governing board of the public healthcare institution for adoption, as well as planning, decision-making, signing public procurement contracts, monitoring and implementation of the public procurements for the needs of
the public healthcare institution, employment in the public healthcare institution, termination of employment of healthcare workers, roster of shifts of healthcare workers and healthcare co-workers and formation of working groups, and adoption of decisions on rewarding all the employees in the public healthcare institutions.

(7) In addition to the requirements referred to in paragraphs (2) and (4) of this Article, the candidates for a director should also meet the requirement for offering the highest quality work program for the public healthcare institution.

(8) The director of the private healthcare institution shall be appointed under the conditions and in a manner determined by a general act of the private healthcare institution.

**Director examination**

**Article 106**

(1) The director examination referred to in Articles 104 paragraph (2) and 105 paragraphs (2) and (3) of this Law shall be taken electronically, in writing, in a form of doing an electronic test on a computer.

(2) The preparation of the candidates for taking the director examination shall be done by the Ministry of Health in cooperation with the appropriate higher education institutions in the Republic of Macedonia.

(3) The costs for preparation of the candidate for a director to take the director examination and the costs for taking the examination shall be covered by the candidate.

(4) The contents of the program and the manner of scoring the first and the second part of the examination, as well as the form and the contents of the certificate, shall be prescribed by the minister of health, in concurrence with the minister of finance.

**Taking a director examination in several parts**

**Article 106-a**

(1) The director examination referred to in Article 106 paragraph (1) of this Law (hereinafter: the director examination) shall consist of two parts, that is:
- first part (theoretical part), based on which the theoretical knowledge of the candidates is checked and
- second part (case study), based on which the practical skills are checked.

(2) The first part of the examination shall be taken electronically, in writing, by answering a particular number of questions in a form of doing an electronic test on a computer by choosing one correct answer from the proposed possible options.

(3) The questions from the first part shall be in the field of public health and health information, health economy and economics in the health sector, health systems and policies, introduction to management and business communication, and human resources management.

(4) The second part of the examination shall consist of:
- a case study and
- answers to the questions in a form of doing an electronic test on a computer that the candidate should answer based on the case study analysis.
Preparation and verification of the questions for the director examination

Article 106-b 14

(1) The databases of the questions for the first part and the databases of the case studies for the second part of the examination shall be prepared by scientific workers holding a title of a doctor of sciences in the field of health and economy, appointed by the minister of health.

(2) The questions from the first part of the examination and the questions and the case studies from the second part of the examination shall be verified by a commission, formed by the minister of health and composed of:
- two representatives from the Ministry of Health and
- five representatives from among the scientific workers holding a title of a doctor of sciences in the field of health, on a proposal of the Government of the Republic of Macedonia.

(3) The commission referred to in paragraph (2) of this Article shall also, at least once a year, review and update the question databases and the case study databases for the examination.

(4) In the course of reviewing, the commission shall particularly take into consideration the changes in the practice and the standards on which the question, that is, the case study is based, the number of candidates that have delivered their answer, the success in answering them, as well as other criteria that may influence the improvement of the quality of the databases referred to in paragraph (1) of this Article.

(5) The commission shall decide to amend or completely remove the questions and the case studies from the databases referred to in paragraph (1) of this Article based on the completed review and update of the questions databases and the case study databases.

(6) The scientific workers referred to in paragraph (1) of this Article and the members of the verification commission referred to in paragraph (2) of this Article shall be entitled to remuneration determined by the minister of health.

(7) The amount of the remuneration referred to in paragraph (6) of this Article shall be determined based on the number of questions and case studies prepared, as well as based on the complexity of the subject.

(8) The annual remuneration referred to in paragraph (6) of this Article shall not exceed the amount of one average salary paid in the Republic of Macedonia in the previous year, announced by the State Statistical Office of the Republic of Macedonia.

Entities responsible for carrying out the professional and administrative activities and for the technical implementation of the director examination

Article 106-c 15

The professional and administrative activities necessary for conducting the examination shall be carried out by the Ministry of Health, and the examination shall be technically implemented by a legal entity registered in the Central Register of the Republic of Macedonia, selected by the Ministry of Health.

Recording of the course of the director examination

Article 106-d 16
(1) The examination shall be taken in premises for taking an examination, equipped separately for taking an examination with material, technical, and IT equipment, internet connection, and equipment for recording the course of the examination.

(2) The taking of the examination shall be recorded and live streamed on the website of the Ministry of Health, and if the recording is interrupted due to technical reasons, the recording of the entire examination shall be posted on the website of the Ministry of Health.

(3) The criteria related to the space, and the material, technical and IT equipment in the premises for taking the examination shall be laid down by the minister of health.

(4) A representative from the Ministry of Health and from the Ministry of Information Society and Administration (computer engineer) shall be present in the premises for taking the examination.

Rules of behavior in the course of the director examination

Article 106-e

(1) Prior to the beginning of the examination, a representative from the Ministry of Health shall establish the identity of the candidate by checking his/her personal identity card and shall keep minutes of the course of the examination.

(2) During the first part of the examination, the candidate shall not be allowed to use professional literature, mobile phone, portable computer devices, and other technical and IT means, and alike.

(3) During the second part of the examination, the candidate shall only be allowed to use professional literature which is available in an electronic version on the computer on which the candidate is taking the examination.

(4) During the first and the second part of the examination, the candidate shall not be allowed to contact other candidates or persons, except the computer engineer referred to in Article 106-d paragraph (4) of this Law in the event of experiencing a technical problem with the computer.

(5) If the technical problems with the computer are eliminated within a period of five minutes, the examination shall continue, but if they are not eliminated within this period, the examination shall be discontinued only for that candidate, and it shall be hold within a period of three days at the most as of the day of discontinuation of the examination.

(6) If problems arise with more than five computers and they are not eliminated within a period of five minutes, the examination shall be discontinued for all of the candidates that are taking the examination, and it shall be hold within a period of three days at the most as of the day of discontinuation of the examination.

(7) If the candidate acts contrary to paragraphs (2), (3), and (4) of this Article in the course of the first and the second part of the examination, he/she shall not be allowed to continue the examination in that specific time period.

(8) In the cases referred to in paragraph (7) of this Article, it shall be regarded that the candidate has not passed the examination which shall be stated in the minutes of the course of the examination.

(9) In the course of the examination, the representatives referred to in Article 106-d paragraph (4) of this Law must not be in the immediate surroundings of the candidate who is taking the examination for more than five seconds, except for elimination of a technical problem when they cannot stay longer than five minutes.
Manner of answering the questions from the director examination and implementation of a single electronic system for examination

Article 106-f

(1) The taking of the first part of the examination shall be done by answering a particular number of questions in a form of an electronic test on a computer.

(2) The questions from the test, depending on its complexity, shall be scored by points set out in the test.

(3) The taking of the second part of the examination shall be done by analyzing the case study and by answering a particular number of questions deriving from the case study, in a form of an electronic software solution (hereinafter: electronic case study).

(4) The questions from the case study, depending on its complexity, shall be scored by points set out in the case study.

(5) The questions contained in the tests of the first part of the examination and their answers, as well as the case study and the questions deriving from the case study and their answers, shall be stored in a single electronic system for taking the examination, implemented by the Ministry of Health.

(6) The electronic system referred to in paragraph (5) of this Article shall also contain a publicly accessible database of at least 300 questions for the first part of the examination, as well as a publicly accessible database of at least 50 case studies for the second part of the examination.

(7) The electronic system referred to in paragraph (5) of this Article shall contain reference to the professional literature in which the answers to the questions from the examination are found.

(8) The number of questions and case studies in the databases referred to in paragraph (6) of this Article shall be annually increased by 10%, starting from 2015.

(9) The results from the first and the second part of the examination shall be available to the candidate on the computer on which he/she is taking the examination, immediately upon its completion.

Manner of taking the director examination

Article 106-g

(1) On the day of taking the first, that is, the second part of the examination, a representative from the Ministry of Health shall provide the candidate with an access code, that is, a password by which his/her access to the electronic system referred to in Article 106-f of this Law is approved.

(2) After being granted the access, the candidate shall be given an electronic test for the first part of the examination, that is, an electronic case study for the second part of the examination, computer-generated, the contents of which, by means of random choice, is determined by the software of the electronic system referred to in Article 106-f of this Law.

(3) The first and the second part of the examination shall contain an instruction for solving the examination, which shall be explained by a representative of the Ministry of Health prior to the beginning of the examination.
Discontinuation, continuation and rescheduling of the director examination

Article 106-h

(1) In the event of prevention for holding the first or the second part of the examination, due to reasons that lead to technical problem for functioning of the electronic system referred to in Article 106-f paragraph (5) of this Law, the examination shall be discontinued.

(2) If the reasons referred to in paragraph (1) of this Article are eliminated within a period of 60 minutes as of the discontinuation of the examination, the examination shall continue immediately after their elimination.

(3) If the reasons referred to in paragraph (1) of this Article are not eliminated within the time period referred to in paragraph (2) of this Article, the examination shall be rescheduled for another date.

Duration of the first and the second part of the director examination and successful passing of the director examination

Article 106-i

(1) The total duration of the time determined for answering the questions from the first part of the test for the examination shall be 90 minutes.

(2) The candidate who earns at least 70% of the total envisaged positive points by giving correct answers to the questions from the test shall be considered to have passed the examination.

(3) The total duration of the time determined for answering the questions from each of the case studies of the second part shall be 90 minutes.

(4) The candidate who earns at least 70% of the total envisaged positive points by giving correct answers to the questions from the case study shall be considered to have passed the examination.

Information about the mistakes made in the test for the director examination

Article 106-j

At a request of the candidate, the Ministry of Health shall inform the candidate about the mistakes made in the test of the examination by providing a direct insight in the test.

Commission for review of held director examinations

Article 106-k

(1) The tests and the case studies shall be used and shall be given to the candidates solely during the examination.
(2) The materials of the examinations held, particularly the paper versions of the tests and the case studies for the examination and the specimens for checking the accuracy of the answers of the test and the case study, as well as the recordings of the examinations held, shall be kept in the Ministry of Health.

(3) The Ministry of Health shall establish a commission for review of the examinations held, which shall use the materials referred to in paragraph (2) of this Article in the course of its work, and the members of which, in addition to a representative from the Ministry of Health, shall be a representative from the Ministry of Finance and a computer engineer from the Ministry of Information Society and Administration.

(4) The commission referred to in paragraph (3) of this Article shall meet at least once a year and shall review the manner of conducting at least two examinations held in the current year.

(5) The commission referred to in paragraph (3) of this Article shall also be entitled to review the manner of conducting the examinations held in the last six months as to the day of holding the meeting of the commission but not earlier than the day of application of this Law.

(6) If the commission referred to in paragraph (3) of this Article establishes irregularities in the conducting of the examination by individuals in terms of Article 106-e paragraph (5) of this Law, it shall propose revocation of the certificate for passed director examination.

(7) The minister of health shall adopt a decision on revocation of the certificate for passed director examination on the basis of the proposal of the commission referred to in paragraph (3) of this Article within a period of three days as of the receipt of the proposal.

(8) An administrative dispute before a competent court may be initiated against the decision referred to in paragraph (7) of this Article within a period of 30 days as of the receipt of the decision.

Appointment and dismissal of a director

Article 107

(1) A director of a public healthcare institution shall be appointed on the basis of a public announcement opened by the governing board of the public healthcare institution.

(2) The director of the public healthcare institution shall be appointed, that is, dismissed by the minister of health.

(3) The minister of health may request an opinion from the Health Council regarding the appointment, that is, the dismissal of the director of the public healthcare institution.

(4) The term of office of the director shall last four years.

Public announcement for selection of a director

Article 108

(1) The governing board of the public healthcare institution, three months before the expiry of the term of office of the current director, shall adopt a decision to open a public announcement which shall be published in at least three daily newspapers published on the whole territory of the Republic of Macedonia, one of which shall be a newspaper published in the language spoken by at least 20% of the citizens who speak an official language other than the Macedonian language.
(2) The opened public announcement shall determine the requirements that should be met by the candidate for a director, the required documentation, and the duration of the announcement.

(3) The minister of health shall adopt a decision on appointment of a director within a period of 30 days as of the day of submission of the documentation referred to in paragraph (2) of this Article.

(4) The candidates who are not selected at the announcement shall have the right to initiate an administrative dispute within a period of eight days as of the day of receipt of the notification.

(5) If no director is appointed at the opened announcement, the minister of health shall, within a period of five days, appoint an acting director until the appointment of a director at an open announcement, but for a period not longer than six months.

Acts and financial documents within the competence of the director

Article 109

(1) The acts and the financial documents within sole competence of the directors of the public healthcare institution referred to in Article 105 of this Law shall be signed solely by the competent director.

(2) The acts and the financial documents within joint competence of the directors of the public healthcare institution referred to in Article 105 of this Law shall be signed by the two directors.

(3) If the act or the financial document referred to in paragraph (2) of this Article is signed only by one of the directors, it shall be considered as not signed at all.

(4) If the act or the financial document is not signed by the two directors within a period of five days, the governing board of the public healthcare institution shall adopt a final decision upon it in the following three days and shall examine at the same time whether the failure to sign it is contrary to this and another law, the statute and the acts of the institution or the director of the public healthcare institution has unjustifiably failed to implement the decisions of the governing board or has acted contrary thereto, that is, whether the failure to sign it is a result of a negligent or incorrect work that causes damage to the healthcare institution or he/she neglects or does not meet the obligations and hence causes disturbance in the performance of the activity of the healthcare institution.

(5) If the governing board establishes existence of some of the grounds for dismissal of the director of the public healthcare institution, it shall notify the healthcare council which is obliged to submit a proposal for dismissal of the director for whom grounds for dismissal are established.

Report on the work of the director

Article 110

(1) The director shall be obliged to submit a report on the work to the minister of health every six months.

(2) In the report referred to in paragraph (1) of this Article, the director shall be obliged to submit particularly data about the type and scope of rendered health services and about the financial operation of the public healthcare institution.

(3) If irregularities and/or losses in the financial operations are established on the basis of the report on the work, the director shall be obliged to eliminate them in the following six months.
(4) If the director fails to eliminate the established irregularities even after the expiry of the following six months and if there are still irregularities and/or losses in the financial operations within that period, the minister of health shall dismiss the director and shall appoint an acting director until the appointment of a director at an open announcement, but for a period not longer than six months.

(5) If the director fails to conduct a procedure for public procurement of medicaments, consumables and medical devices, the minister of health shall instruct the director to initiate a procedure for public procurement within a period of 15 days.

(6) If the director does not initiate a procedure for public procurement following the expiry of the time period referred to in paragraph (5) of this Article, the minister shall give him/her an additional period of 15 days to initiate a procedure for public procurement.

(7) If the director does not initiate a procedure for public procurement upon the expiry of the time period referred to in paragraph (6) of this Article, the minister of health shall dismiss the director and shall appoint an acting director until the appointment of a director at an open announcement, but for a period not longer than six months.

(8) If the director does not implement the regulations pertaining to the sanitary and hygienic requirements in the healthcare institutions, the minister of health shall instruct the director to ensure complete implementation of the regulations pertaining to the sanitary and hygienic requirements in the healthcare institutions within a period of 15 days.

(9) If the director does not fully implement the regulations pertaining to the sanitary and hygienic requirements in the healthcare institutions after the expiry of the time period referred to in paragraph (8) of this Article, the minister shall give him/her an additional period of 15 days for the director to ensure complete implementation of the regulations pertaining to the sanitary and hygienic requirements in the healthcare institutions.

(10) If the director does not ensure complete implementation of the regulations pertaining to the sanitary and hygienic requirements in the healthcare institutions after the expiry of the time period referred to in paragraph (9) of this Article, the minister of health shall dismiss the director and shall appoint an acting director until the appointment of a director at an open announcement, but for a period not longer than six months.

(11) A person who meets the requirements referred to in Article 104 paragraph (2) of this Law, except the requirement for offering the highest quality work program for the public healthcare institution, shall be appointed as acting director.

**Dismissal of a director**

**Article 111**

(1) The director of a public healthcare institution may be dismissed prior to the expiry of the time period for which he/she is appointed:

1) at his/her personal request;

2) in the case of appearance of any of the reasons due to which, according to the regulations in the field of employment, his/her employment terminates in accordance with law;

3) if he/she works or acts contrary to this and another law, the statute and the acts of the institution, or without any justification he/she does not implement the decisions of the governing board or acts contrary thereto;

4) if his/her negligent and incorrect work causes damage to the institution or if, due to negligence or non-fulfillment of the obligations, the performance of the activity of the institution is disturbed;

5) if the institution ends two consecutive six-month periods with losses in its financial operation;

6) if the program referred to in Article 148 paragraph (2) of this Law is not adopted and/or he/she does not ensure its implementation, that is, he/she does not provide funds in the amount necessary
for the implementation of the specializations, that is, sub-specializations out of the funds of the healthcare institution;
7) if he/she does not implement the recommendations of the expert supervision conducted;
8) in the case of greater employment than the one planned with the work program of the public healthcare institution;
9) due to payouts for overtime work higher than the ones actually done and for contractual obligations other than those planned;
10) if he/she obstructs the exercise of the rights and obligations of the beneficiaries of health protection; and
11) if he/she does not submit a regular six-month report on the work.

(2) In the cases referred to in paragraph (1) points 3 to 11 of this Article, the minister of health shall dismiss the director for whom the existence of grounds for dismissal have been established.

(3) If the director is dismissed in accordance with paragraph (1) of this Article, the minister of health shall appoint an acting director until the appointment of a director at an open announcement, but for a period not longer than six months.

(4) The dismissed director shall have the right to initiate an administrative dispute within a period of eight days as of the day of receipt of the decision.

**Professional collegium**

**Article 112**

(1) The public healthcare institution shall have a professional collegium, which shall be a professional body of the institution.

(2) The professional collegium shall propose needs for procurement of medicaments, medical devices and other consumables necessary for carrying out the healthcare activity of the public healthcare institution to the director, in accordance with the work program, and it shall perform other activities determined by the statute of the institution.

(3) The professional collegium shall be composed of the director, the heads of the basic organizational units, and the head nurse.

**Planning and financial operation**

**Article 113**

(1) A public healthcare institution shall provide funds for work:
- from the payments for the provided health services, that is, from the health services programs on the basis of an agreement with the Fund,
- from the payments for the implemented measures, activities and provided health services under the programs referred to in Article 16 of this Law,
- from the payments for health services within the healthcare activity for patients who cover the services by their own funds,
- from the participation with own funds of the insured persons for health services covered by the mandatory health insurance, that is, surcharge for higher standard of health services, in accordance with the regulations in the field of health insurance,
- from the funds of the insurance companies providing voluntary additional health insurance,
- from the funds of the founder earmarked for investments and other activities,
- from donations and gifts, and
- from other sources, under conditions determined by law.
(2) The public healthcare institution shall be obliged to ensure concordance between the expenditures of the public healthcare institution and its incomes.

(3) A public healthcare institution that performs also a healthcare activity for patients who cover the services by their own funds shall keep the incomes and the expenditures, as well as the funds and fund resources, generated in relation to the performance of that activity, separately from the incomes and expenditures generated by the performance of the healthcare activity in the network.

(4) The possible surplus of income over expenditures that the public healthcare institution gains by performing the activity referred to in paragraph (3) of this Article shall be earmarked for development of the health services and the healthcare activity.

(5) The governing board of the institution shall decide on the allocation of the surplus of the income over expenditures on a proposal of the director and in accordance with the founder.

**Elements of the work program and the financial plan**

**Article 114**

(1) The healthcare activity in the public healthcare institution shall be carried out in accordance with the work program and the financial plan for incomes and expenditures that ensures completion of the program objectives and operation of the public healthcare institution within the limits of the available financial and other sources, gained by the institution by the performance of the healthcare activity.

(2) The acts referred to in paragraph (1) of this Article shall particularly determine:
- the personnel, spatial and other capacities of the public healthcare institution and its organizational units,
- the scope and type of health services and the other obligations of the public healthcare institution as a whole and its organizational units,
- the scope of the on-duty work and the readiness, that have to be performed by the healthcare workers under the emergency medical care,
- the plan for professional education and training,
- the planning of health services provided outside the healthcare activity in the network, in the cases where the institution provides such services,
- the investment plans and the plan for investment sustainability, and
- the planned incomes according to sources and expenditures of the performance of the healthcare activity per organizational unit and at the level of the institution.

(3) The governing board of the public healthcare institution shall adopt the program referred to in paragraph (1) of this Article upon a previous opinion of the professional collegium.

**VII. HEALTHCARE WORKERS AND HEALTHCARE CO-WORKERS**

**1. Requirements for performance of a healthcare activity**

**Healthcare workers and healthcare activity co-workers**

**Article 115**

(1) The healthcare workers with a university degree in the field of medicine, dental medicine and pharmacy (hereinafter: the healthcare workers with a university degree) may independently provide health services by completing the probationary work, passing the expert examination and obtaining a license for work.
(2) The healthcare workers with secondary education, two-year post secondary education and higher vocational education in the field of medicine, dental medicine and pharmacy (hereinafter: the healthcare workers with secondary education, two-year post secondary education and higher vocational education) may independently provide health services upon completion of the probationary work and passing the expert examination.

(3) Particular health services under the healthcare activity may be independently provided by healthcare workers with appropriate specialization, that is, subspecialization, and with a license for work, as well as healthcare co-workers with appropriate specialization, that is, subspecialization, in accordance with the provisions of this Law.

(4) The healthcare co-workers with a university degree may independently carry out particular works under the healthcare activity upon completion of the probationary work and passing the expert examination.

(5) In addition to the requirements referred to in paragraphs (1), (2) and (3) of this Article, the healthcare workers should also be entered in the register of healthcare workers referred to in Article 116 of this Law.

(6) The types of profiles of personnel, the levels of education, the fields of work and degree of complexity of the work within the healthcare activity shall be prescribed by the minister of health.

(7) The healthcare workers and healthcare co-workers referred to in paragraphs (2) and (4) of this Article cannot be holders of a healthcare activity in healthcare institutions.

Register of healthcare workers

Article 116

(1) The register of healthcare workers shall be kept in an electronic form by the Institute for Public Health of the Republic of Macedonia, in accordance with this Law and the regulations in the field of health records.

(2) The register referred to in paragraph (1) of this Article shall contain the following data about the healthcare worker:
- name and surname;
- date and place of birth;
- personal identification number of the citizen (PIN);
- address of the permanent place of residence, that is, temporary place of residence;
- citizenship;
- education background;
- data on the passed expert examination;
- data on specialization, that is, subspecialization and additionally acquired knowledge;
- license data,
- seal number,
- data on professional, that is, scientific title, and employment data.

(3) The data referred to in paragraph (2) lines 1 to 9 of this Article shall be entered in the register of healthcare workers by the corresponding chamber.

(4) The data about the employment and the specialization, that is, scientific title shall be entered by the Institute of Public Health, on a proposal of the healthcare institution where the healthcare worker is employed.
(5) The register of healthcare workers shall be used by the Ministry of Health, the competent inspections and the competent chambers within the limits of the delegated public powers.

(6) The manner of entry in the register of healthcare workers shall be prescribed by the minister of health.

**Probationary work of healthcare workers**

**Article 117**

(1) The healthcare institutions may admit healthcare workers, that is, healthcare co-workers on probationary work and training for passing the expert examination.

(2) The probationary work of healthcare workers with a university degree in the field of medicine and dental medicine who have completed five-year studies, that is, four-year studies in the field of pharmacy shall last one year, and of healthcare workers with a university degree in the field of medicine who have completed six-year studies shall last six months, and of healthcare workers with a university degree in the field of dental medicine who have completed six-year studies and five-year studies in the field of pharmacy shall last six months.

(3) The probationary work of healthcare workers with a higher vocational education shall last ten months, nine months of healthcare workers with a two-year post secondary education, and six months of those with a secondary school education.

(4) The probationary work of healthcare co-workers with a university degree shall last ten months.

**Plan and program for probationary work of healthcare workers**

**Article 118**

(1) The plan and the program for probationary work of healthcare workers with a university degree, the form and the manner of keeping a booklet of probationary work shall be prescribed by the minister of health on a prior opinion of the Doctors’ Chamber of Macedonia, the Dental Chamber of Macedonia, that is, the Pharmaceutical Chamber of Macedonia (hereinafter: the Doctors’, Dental, that is, Pharmaceutical Chamber).

(2) The plan and the program for probationary work of healthcare workers with secondary education, two-year post secondary education and higher vocational education, the form and the manner of keeping the booklet for probationary work, the composition of the examination commission, the manner of taking the expert examination, and the form of the certificate for a passed expert examination shall be prescribed by the minister of health, upon a prior opinion of the corresponding chamber.

(3) The plan and the program for probationary work of healthcare co-workers with a university degree, the form and the manner of keeping the booklet for probationary work, the composition of the examination commission, the manner of taking the expert examination, and the form of the certificate for a passed expert examination shall be prescribed by the minister of health.

**Educator for probationary work**

**Article 119**

(1) The probationary work of healthcare workers and healthcare co-workers shall be done in healthcare institutions according to the plan and the program referred to in Article 118 of this Law,
through practical training and under supervision of an authorized healthcare worker, that is, healthcare co-worker (hereinafter: the educator for probationary work).

(2) The educator referred to in paragraph (1) of this Article shall be obliged to keep records of the trainee period and to ensure the implementation of the probationary work plan and program.

Criteria for an educator for probationary work

Article 120

(1) The educators for probationary work, who hold a corresponding higher education degree and have corresponding work experience in the appropriate field of specialization, under the supervision of whom the probationary work of the healthcare workers with a university degree is done, shall be determined by the Doctors’, Dental, that is, Pharmaceutical Chamber.

(2) The detailed criteria that should be met by the educators for probationary work regarding the education and the work experience referred to in paragraph (1) of this Article shall be determined by the Doctors’, Dental, that is, Pharmaceutical Chamber by an act consented by the minister of health.

(3) The detailed criteria that should be met by the educators for probationary work regarding the education and the work experience, under the supervision of whom the probationary work of the healthcare workers with secondary education, two-year post secondary education and higher vocational education and of healthcare co-workers with a university degree is done, shall be prescribed by the minister of health.

Expert examination for healthcare workers and co-workers

Article 121

(1) Upon completion of the probationary work, the healthcare workers and the healthcare co-workers shall be obliged to take an expert examination within a period of one year as of the day of completion of the probationary work plan and program.

(2) If the healthcare workers and the healthcare co-workers do not take an expert examination within the period referred to in paragraph (1) of this Article, they shall do the probationary work again.

(3) The healthcare workers with a university degree shall take the expert examination before examination commissions formed by the Doctors’, Dental, that is, Pharmaceutical Chamber.

(4) The expert examination of the healthcare workers with secondary education, two-year post secondary education and higher vocational education and the healthcare co-workers with a university degree shall be taken before examination commissions established by the minister of health.

(5) The composition of the examination commission, the manner of taking the examination, the manner of checking the acquired knowledge and skills, and the forms of the certificate for a passed expert examination of the healthcare workers with a university degree shall be determined by the Doctors’, Dental, that is, Pharmaceutical Chamber by a general act consented by the minister of health.

Recognition of the probationary work and the expert examination taken and passed abroad

Article 122
(1) The probationary work and the expert examination of healthcare workers and healthcare co-workers who have taken and passed them abroad may be completely or partially recognized if the program for the completed trainee period, that is, the program for taking the expert examination does not differ from the probationary work program, that is, the program for expert examination adopted on the basis of this Law.

(2) The recognition of the probationary work and the expert examination referred to in paragraph (1) of this Article of healthcare workers with a university degree shall be done by the Doctors’, Dental, that is, Pharmaceutical Chamber, and by the Ministry of Health regarding the healthcare workers with secondary education, two-year post secondary education and higher vocational education and of healthcare co-workers with a university degree.

2. Issuance, renewal, extension and revocation of a license for work

Competence of the chambers

Article 123

(1) The license for work of healthcare workers with a university degree shall be issued, renewed, extended and revoked by the Doctors’, Dental, that is, Pharmaceutical Chamber for the purpose of establishing the expert competence of the healthcare workers for independent work.

(2) The license for work shall be issued for a period of seven years.

Obtaining a license

Article 124

(1) A healthcare worker with a university degree may obtain a license for work if he/she holds:
1) a diploma for completed appropriate education in the field of medicine, dental medicine, that is, pharmacy, and
2) a proof of a completed probationary work and a certificate for a passed expert examination.

(2) A healthcare worker with a university degree, who has completed the probationary work and has passed the expert examination abroad may obtain a license for work if he/she holds:
1) a validated diploma for completed corresponding education, and
2) a proof of recognized probationary work and a passed expert examination.

(3) A healthcare worker with a university degree who has obtained a license for work abroad may obtain a license for work if, in addition to the requirements referred to in paragraph (2) of this Article, he/she also has:
1) a recommendation from the chamber where he/she has been a member, and
2) a proof for previous work experience in the field in which he/she requests a license for work.

License for work in the specialization and subspecialization branch

Article 125

The healthcare worker with a university degree, upon completion of the corresponding specialization, that is, subspecialization, may obtain a license for work in the corresponding specialization, that is, subspecialization branch.

Obtaining a license for a healthcare worker – foreign citizen
Article 126

(1) A healthcare worker with a university degree – a foreign citizen may obtain a license for work if, in addition to the general requirements determined by the regulations in the field of movement, residence and employment of foreigners, he/she also meets the requirements laid down in this Law for citizens of the Republic of Macedonia who have completed their education abroad and if he/she has completed an additional training and had the expert knowledge and skills checked in accordance with the Program for Additional Training and Check of the Expert Knowledge and Skills referred to in Article 127 of this Law.

(2) As an exception to paragraph (1) of this Article, a healthcare worker with a university degree who has acquired his/her qualifications in the member states of the European Union or in Switzerland, Norway, Canada, Japan, Israel, Turkey, Russia or USA is not required to have additional training and check of the expert knowledge and skills determined in the program referred to in paragraph (1) of this Article, as well as to meet the requirement referred to in Article 128 of this Law.

Program for additional training and check of the expert knowledge and skills

Article 127

(1) The program for additional training and check of the expert knowledge and skills of the healthcare workers with a university degree, the composition of the examination commission, and the manner of conducting the examination shall be determined by the Doctors’, Dental, that is, Pharmaceutical Chamber by an act consented by the minister of health.

(2) The check referred to in paragraph (1) of this Article shall be carried out by the Doctors’, Dental, that is, Pharmaceutical Chamber.

Other requirements for a healthcare worker – a foreign citizen

Article 128

(1) A healthcare worker with a university degree – a foreign citizen who carries out a healthcare activity in the Republic of Macedonia, in addition to the requirements prescribed in Article 126 of this Law, must have a good command of the Macedonian language.

(2) The healthcare worker with a university degree referred to in paragraph (1) of this Article shall prove his/her knowledge of the language by a certificate for a successfully passed language examination from an authorized education institution.

Renewal of the license

Article 129

(1) A healthcare worker with a university degree may get his/her license for work renewed if, during the validity period of the license, he/she has acquired an appropriate number of scores through continuous professional development, staying current with the innovations in the medicine, dental medicine, that is, pharmacy, and upgrading the personal knowledge, and if he/she has spent at least 60% of the validity period of the license for work working in the field for which a license for work has been obtained.
(2) As an exception to paragraph (1) of this Article, a healthcare worker with a university degree elected or appointed to a public office shall not have the time spent in office calculated in the validity period of the license for work determined in paragraph (1) of this Article.

(3) The forms of continuous professional development, the criteria for distribution of the forms, the criteria for selection of those delivering the continuous professional development forms, and the scores referred to in paragraph (1) of this Article shall be determined by the Doctors’, Dental, that is, Pharmaceutical Chamber by a general act consented by the minister of health.

**Temporary extension of the license**

**Article 130**

(1) The license for work of a healthcare worker with a university degree who does not meet the requirements referred to in Article 129 of this Law may be temporarily extended for the following six months, provided that he/she successfully completes the additional training and the check of the expert knowledge and skills in accordance with the Program for Additional Training and Check of the Expert Knowledge and Skills referred to in Article 127 of this Law in that period.

(2) A healthcare worker with a university degree who does not meet the requirements referred to in paragraph (1) of this Article may be temporarily revoked the license.

**Re-obtaining a license of a healthcare worker whose license has been temporarily revoked**

**Article 131**

A healthcare worker with a university degree who has been temporarily revoked the license for work may re-obtain the license if, during the year following the expiry of the validity periods determined by this Law, he/she completes additional training in accordance with the Program referred to in Article 127 of this Law and successfully passes the additional check of the expert knowledge and skills before an examination commission of the corresponding chamber.

**Temporary or permanent revocation of the license**

**Article 132**

(1) The Doctors’, Dental, that is, Pharmaceutical Chamber may temporary or permanently revoke the license for work of a healthcare worker with a university degree.

(2) The license for work of a healthcare worker with a university degree may be temporary revoked for a period of seven years at the most if the healthcare worker:  
1) does not extend the license for work within the deadlines determined by this Law;  
2) does not complete the additional training within the determined deadline;  
3) does not complete the additional check of the expert knowledge and skills successfully;  
4) has a legally valid court decision whereby he/she is temporarily prohibited to perform duty or practice profession;  
5) has obtained the evidence for meeting the requirements prescribed by this Law contrary to law and it is determined after the license for work has been granted;  
6) performs additional activity contrary to Articles 222 and 223 of this Law;  
7) works outside the license for work remit or works in conditions for which he/she does not hold a license for work issued in accordance with this Law; and  
8) have committed a violation of the Code of Medical Ethics and Deontology which has been established by the Court of Honor of the corresponding chamber.
9) renders health or consultative services and/or concludes a contract for provision of health or consultative services with private health institutions contrary to Article 167-a of this Law.

(3) In the case referred to in paragraph (2) points 6 and 9 of this Article, a healthcare worker with a university degree shall be revoked his/her license for work for a period of four years and he/she cannot perform an additional activity within a period of two years as of the day of reissuance of the license for work.

(4) The license for work of a healthcare worker with a university degree shall also be temporarily revoked for a period determined by the Doctors', Dental, that is, Pharmaceutical Chamber if it is established that the healthcare worker with a university degree has committed a crime related to the performance of the healthcare activity by a legally valid court decision.

(5) The decision on temporary revocation of the license for work shall determine the additional training that the healthcare worker with a university degree should complete in accordance with the Program referred to in Article 127 of this Law and should successfully complete the additional check of the expert knowledge and skills before an examination commission of the corresponding chamber in order to be reissuied the license for work.

(6) The license for work shall be permanently revoked if it is established that the healthcare worker with a university degree has committed a professional fault or mistake at work which caused permanent health deterioration or death of the ill by a legally valid court decision.

Right to appeal the decision on temporary and permanent revocation of the license

Article 133

The healthcare worker with a university degree shall have the right to file an appeal against the decision on temporary and permanent revocation of the license for work to the minister of health within a period of 15 days as of the day of receipt of the decision.

Re-obtaining a license

Article 134

(1) A healthcare worker with a university degree referred to in Article 132 paragraph (2) of this Law may re-obtain the license for work if, during two years after the expiry of the validity periods determined in this Law, he/she completes an additional training and successfully completes the additional check of the expert knowledge and skills in accordance with the Program referred to in Article 127 of this Law before an examination commission of the corresponding chamber.

(2) If a healthcare worker with a university degree does not obtain a license for work within the period referred to in paragraph (1) of this Article, he/she may re-obtain the license for work in the case he/she completes an additional training and successfully completes the additional special check of the expert knowledge and skills in accordance with the Program referred to in Article 127 of this Law before an examination commission of the corresponding chamber.

License-related act

Article 135

The manner of issuance, extension, renewal and revocation of the license for work and the form and contents of the form of the license for work of the healthcare workers shall be in detail determined by
the Doctors’, Dental, that is, Pharmaceutical Chamber by a general act consented by the minister of health.

**Costs**

**Article 136**

(1) The costs for issuance, extension and renewal of the license for work shall be covered by the requesting entity.

(2) Basic criteria for determining the costs shall be the actual administrative and material costs for implementation of the procedure for issuance, extension and renewal of the license for work.

(3) The amount of the costs referred to in paragraph (2) of this Article shall be determined by the Doctors’, Dental, that is, Pharmaceutical Chamber by a general act consented by the minister of health.

(4) The minister of health may withdraw the consent referred to in paragraph (3) of this Article in the event of a change of the costs on the basis of which the amount of the costs for issuance, extension and renewal of the license for work is established, in which case the corresponding chamber shall be obliged, within a period of 15 days as of the withdrawal of the consent, to adopt a new general act to establish the amount of the costs referred to in paragraph (2) of this Article, consented by the minister of health.

(5) Upon expiry of the period referred to in paragraph (4) of this Article, the general act referred to in paragraph (3) of this Article whose consent has been revoked by the minister of health shall cease to be valid.

**3. Primarius**

**Requirements for awarding the title of primarius**

**Article 137**

(1) The healthcare workers with a university degree who have at least 15 years of successful work in the promotion, organization and implementation of health protection, passed specialty examination, published professional or scientific papers, positive results in the expert training of personnel, and opinion of the corresponding chamber, may be awarded the title of primarius.

(2) The title of primarius may also be awarded to doctors of medicine, doctors of dental medicine and graduated pharmacists even if they have not passed the specialty examination, but they meet the requirements referred to in paragraph (1) of this Article and have at least 15 years of successful work.

(3) The title of primarius shall be awarded by a special commission formed by the minister of health.

(4) The commission referred to in paragraph (3) of this Article shall be composed of seven members from among the prominent health and scientific workers.

(5) The detailed criteria for awarding the title of primarius referred to in paragraph (1) of this Article shall be determined by the minister of health.

**4. Specializations and subspecializations**
Right to specialization and subspecialization

Article 138

(1) The healthcare workers and the healthcare co-workers with a university degree may specialize and subspecialize within particular branches of medicine, dental medicine, that is, pharmacy.

(2) The branches of specializations and subspecializations, their duration, the parts of the residency (modules), the plans and programs, as well as the manner of doing the residency, the manner of taking the examination, and the form of the resident booklet and of the book of records of completed procedures and interventions during the residency shall be prescribed by the minister of health on a prior opinion of the corresponding higher education institution.

Manner of carrying out

Article 139

The specialization and subspecialization of healthcare workers with a university degree and healthcare co-workers with a university degree shall be carried out in accordance with the plans and programs referred to in Article 138 paragraph (2) of this Law.

Manner of delivery

Article 140

(1) The specialization and the subspecialization shall be delivered by lectures and practical training during specific period of time in the corresponding higher education and healthcare institutions.

(2) The fee for delivering lectures and practical training and for taking the specialty examination referred to in paragraph (1) of this Article shall be determined by the Government on a proposal of the minister of health based on the amount of the material costs for delivery of the specialization and the remuneration for the people engaged in the delivery of the lectures and the practical work, and shall be covered by the institution referring them to specialization, in accordance with the program for the needs of specialized personnel.

(3) 50% of the funds from the fee referred to in paragraph (2) of this Article shall be earmarked for the higher education institution where the specialization is delivered, and 50% for the healthcare institution where the residency is carried out. The higher education institution and the healthcare institution shall be obliged to use the funds that they receive for delivery of the specialization exclusively for development of the higher education, that is, healthcare activity. 90% of the funds received by the higher education institutions for delivery of the specialization shall be earmarked for the mentors and educators, and 10% for the higher education institution, on the basis of a decision of the higher education institution.

(4) The minister of health shall prescribe the organizational, personnel, material and other detailed criteria, depending on the type of specialization delivered, that should be met by the healthcare institutions.

(5) The minister of health shall, in cooperation with the higher education institutions in the field of medicine, dental medicine and pharmacy, on the basis of the criteria referred to in paragraph (4) of this Article, determine the healthcare institutions where the specialization and subspecialization of healthcare workers and co-workers with a university degree is to be delivered.

Prerequisite
Article 141

(1) The healthcare workers with a university degree may specialize if they have completed the probationary work, have passed the expert examination and hold a license for work.

(2) The health co-workers with a university degree may specialize if they have completed the probationary work, have passed the expert examination and have one year of work experience in the profession following the passing of the expert examination.

Mentor

Article 142

(1) The implementation of the plan and the program for specializations and subspecializations by healthcare workers with a university degree, that is, healthcare co-workers with a university degree (hereinafter: the residents) shall be organized and monitored by an authorized healthcare worker, that is, healthcare co-worker (hereinafter: the mentor) who meets the criteria with regard to the education and experience in the corresponding field of specialization, that is, subspecialization.

(2) During the implementation of the plan and the program for specializations and subspecializations, the mentor shall also ensure additional activities and shall be responsible, in cooperation with the authorized healthcare worker, that is, healthcare co-worker referred to in Article 144 of this Law, to provide the resident with the skills under the plan and program for specializations, that is, subspecializations, and the resident to succeed in acquiring the knowledge and skills during the specialization, that is, subspecialization.

(3) The mentor shall have the role of a guide of the resident in carrying out the specialization, that is, the subspecialization, and may guide three residents at the most, that is, six residents in family medicine.

(4) The mentor referred to in paragraph (1) of this Article may guide three more residents at the most, that is, six more residents in family medicine from among the healthcare workers, that is, healthcare co-workers employed in private healthcare institutions, that is, other legal entities and unemployed persons.

(5) If the mentor does not provide the resident with the skills under the plan and program for specialization, that is, subspecialization, he/she cannot guide another resident.

(6) The healthcare workers and healthcare co-workers referred to in paragraph (1) of this Article shall be authorized by the minister of health upon a proposal of the faculty of medicine, the dental medicine, that is, the faculty of pharmacy.

(7) The detailed criteria referred to in paragraph (1) of this Article shall be prescribed by the minister of health.

Modules

Article 143

(1) The mentor referred to in Article 142 of this Law shall confirm the successfully acquired part of the specializations and subspecializations (module), which gives the resident an opportunity to continue with the specialization, that is, subspecialization in accordance with the plan and program.
(2) If the resident does not successfully acquire the part of the specialization, that is, subspecialization (the module), the duration of the specialization shall be expanded for the time necessary to acquire the appropriate part of the specialization, that is, subspecialization (hereinafter: the repeated module).

(3) The resident shall be obliged to repeat the entire or part of the module if the mentor assesses that he/she has not successfully acquired the knowledge and skills under the plan and program.

(4) The implementation of the repeated module or part of the module shall be covered by the resident.

Educator

Article 144

(1) The residents shall acquire and achieve particular skills under the plan and program for specializations, that is, subspecializations in healthcare institutions referred to in Article 140 paragraph (1) of this Law, under the supervision of an authorized healthcare worker, that is, healthcare co-worker (hereinafter: the educator), who meets the criteria for the education and experience in the corresponding area of specialization, that is, subspecialization.

(2) The residents may provide, that is, carry out particular works in the provision of health protection in the area of specialization, that is, subspecialization only under the supervision of their educator.

(3) The educator, in coordination with the mentor, may guide three residents at the most in the parts of the specialization, that is, subspecialization for which he/she has been appointed, and shall confirm the acquisition and achievement of particular skills under the plan and program for specializations, that is, subspecializations.

(4) The detailed criteria referred to in paragraph (1) of this Article shall be prescribed by the minister of health.

Specialty and subspecialty examination

Article 145

After mastering the plan and the program for specialization, that is, subspecialization, the resident, in the presence of the mentor, shall take a specialty, that is, subspecialty examination that consists of a written, oral and practical part, before an examination commission established by the faculty of medicine, of dental medicine, that is, the faculty of pharmacy.

Revocation of the authorization of the mentor and the educator

Article 146

If at least two residents with the same mentor, that is, educator have failed to successfully acquire the particular skills under the plan and program for specializations, that is, subspecializations during a period of five years, the mentor, that is, the educator shall be revoked the authorization to perform the activities of a mentor, that is, educator.

Agreement between the public healthcare institution and the resident

Article 147
(1) The public healthcare institution that have approved the specialization shall conclude an agreement with the resident, regulating the mutual rights and obligations concerning the implementation of the specialization, the time that the resident needs to spend working in the institution after the completion of the specialization, and that, regarding the specializations that last up to five years, the resident should work in the institution for at least ten years, and that, regarding the specializations that last more than five years, the resident should work in the institution for at least 15 years, the amount of the funds that should be compensated in the case of early leave of the institution upon his/her personal request or due to his/her fault, and the appropriate guarantee in case of non-fulfillment of the obligation towards the healthcare institution.

(2) The funds for salaries, the payment of contributions for social insurance, the funds for salary compensations in case of temporary absence from work due to illness or injuries, and the other costs with regard to the job and the specialization of the residents shall be provided by their employers.

(3) The amount of the funds that should be compensated by the resident in case of early leave from the institution that has referred him/her to specialization referred to in paragraph (1) of this Article upon his/her personal request or due to his/her fault cannot be lower than ten times the amount of the specialization that is paid by healthcare workers employed in a private healthcare institution, other legal entities or unemployed persons at the moment they leave the institution.

Criteria and program for the needs of specialized and subspecialized personnel

Article 148

(1) The Government of the Republic of Macedonia shall adopt a four-year program for the needs of specialist and subspecialist personnel in accordance with the network of healthcare institutions. The need of specialist and subspecialist personnel shall be determined in the program each year separately.

(2) For the purpose of implementing the program, the public healthcare institutions shall be obliged to ensure finances in the amount required for delivery of the specializations, that is, subspecializations.

(3) The program referred to in paragraph (1) of this Article shall be adopted upon a proposal of the Specializations Council formed by the minister of health.

(4) The Specializations Council shall be composed of nine members, one member proposed by each of the Doctors’, Dental, that is, Pharmaceutical Chamber, four members proposed by the Ministry of Health and one member proposed by each the Ministry of Education and Science and the Fund. The members proposed by the Doctors’, Dental, that is, Pharmaceutical Chamber should be from among the part-time or full-time professors in the corresponding field.

(5) The principle of equitable representation of all the communities in the Republic of Macedonia shall apply to the selection of the members of the Specializations Council.

Program for professional development in the healthcare institutions in the network

Article 149

(1) The healthcare institutions in the network shall adopt a program for professional development which shall be harmonized with the program referred to in Article 148 of this Law.
(2) The specialization, that is, the subspecialization of healthcare workers and healthcare co-workers may be planned and approved only within the branches of medicine, dental medicine, pharmacy and other areas that are part of the activity of the healthcare institution and of the legal entity.

(3) The healthcare institutions that provide health protection shall refer healthcare workers and healthcare co-workers to specialization, that is, subspecialization, in a procedure and in a manner determined by their general acts in accordance with the programs referred to in Article 148 of this Law.

(4) The public healthcare institution, in the act referred to in paragraph (1) of this Article, shall determine the scores for selection of candidates who meet the requirements referred to in Article 141 of this Law for the order of referring to specialization, that is, subspecialization by means of a public or internal announcement for specialization, that is, subspecialization of the employees in the public healthcare institution referring them to specialization, that is, subspecialization, according to the following criteria and proportion: 70% for the GPA score of the candidate at the university, 20% for the score from the length of service and 10% for the success achieved in the subject in the field of which the specialization, that is, subspecialization is awarded. The manner of calculating the weighted GPA scores of the candidate at university and the success in the subject shall be determined by the minister of health.

(5) The act for referral to specialization, that is, subspecialization, together with the proofs for meeting the requirements and a proof of approval of the specialization, that is, subspecialization in accordance with the programs referred to in paragraph (1) of this Article shall be submitted by the healthcare institution to the appropriate higher education institution for the purpose of enrolling in specialization, that is, subspecialization.

(6) The higher education institutions shall keep records of the healthcare workers, that is, healthcare co-workers who have been referred, have applied for enrollment and who are attending specialization, that is, subspecialization, as well as of the fulfillment of the specialization, that is, subspecialization program.

(7) The higher education institutions, on the basis of the records referred to in paragraph (6) of this Article, shall be obliged to enroll the healthcare workers, that is, healthcare co-workers in specialization, that is, subspecialization according to the order of applying, the criteria established by the higher education institution and if they meet the requirements referred to in Article 141 of this Law, and within the announced number of vacancies for performing specializations, that is, subspecializations announced in the mass media.

Specialization opportunity of healthcare workers and co-workers from private healthcare institutions

Article 150

The healthcare workers, that is, healthcare co-workers employed in private healthcare institutions, other legal entities and unemployed persons may apply for enrollment in specialization, that is, subspecialization in accordance with the specialization plan adopted by the higher education institution, provided that they meet the requirements referred to in Article 141 of this Law and the criteria determined by the higher education institution.

Specialization of a foreign citizen – a healthcare worker

Article 151
(1) The Ministry of Health may approve specialization, that is, subspecialization of a foreign citizen – a healthcare worker who holds a degree from the faculty of medicine, dental medicine, that is, faculty of pharmacy.

(2) The Ministry of Health shall recognize the specializations and subspecializations completed abroad.

(3) In order to recognize the specializations and subspecializations completed abroad, the minister of health shall form commissions for specific areas, composed of five members in the respective area, at least two of whom shall be university professors, and the expert and administrative and technical activities of the commission shall be carried out by the Ministry of Health.

(4) The manner of recognizing and the documents required for recognition of the specializations and subspecializations completed abroad, as well as the manner of keeping records of the recognized specializations and subspecializations completed abroad, shall be prescribed by the minister of health.

5. Duties of healthcare workers and healthcare co-workers

Liability of the healthcare worker

Article 152

(1) The healthcare worker shall be ethically, professionally and materially liable.

(2) The healthcare institution shall take out liability insurance for the healthcare workers against damage they could possibly cause in the performance of the healthcare activity.

Professional secret

Article 153

(1) The healthcare workers and healthcare co-workers shall have rights and duties regulated by this and another law.

(2) The healthcare workers shall be obliged to keep as a professional secret everything they know about the health condition of the patient.

(3) The other employees in the health sector, as well as the students and pupils, shall also be obliged to keep the professional secret they become familiar with while on duty.

(4) The professional secret shall be obliged to keep also all the other persons who find data about the health condition of a patient in the course of performance of their duty.

Violation of professional secret

Article 154

(1) A violation of professional secret shall constitute a violation of the obligations under employment.

(2) The regulations in the field of health records, protection of patients’ rights, and personal data protection shall apply to the keeping, storing, collecting and dealing with the medical documentation.

Conscientious objection
Article 155

(1) The healthcare worker, by reason of his/her ethical or moral views or by reason of his/her belief, may refuse to provide a particular health service, unless it is in accordance with his/her conscience.

(2) The healthcare worker shall be obliged to inform the employer about his/her conscientious objection when concluding the employment contract and the employer shall be obliged to take that into consideration and to provide the patients the health service.

(3) If the healthcare worker is the single holder of the healthcare activity, he/she shall be obliged to refer the patient to another healthcare institution that would provide him/her the health service.

(4) The healthcare worker cannot exercise the conscientious objection in case of provision of emergency medical care.

5-a. Providers of public health services

Classification of positions

Article 155-a

(1) The employees in the public healthcare institutions that carry out works related to the healthcare activity shall have the status of providers of public health services and the provisions of this Law, the provisions of the Law on Public Sector Employees, and the general regulations on labor relations shall apply to them.

(2) The following categories of positions shall be determined for the employees referred to in paragraph (1) of this Article:

- category A - healthcare workers with a higher education in the field of medicine, dentistry and pharmacy,
- category B - healthcare workers with a higher vocational education in the field of medicine and dentistry,
- category C - healthcare workers with a two-year post-secondary vocational education in the field of medicine and dentistry,
- category D - healthcare workers with a secondary education in the field of medicine, dentistry and pharmacy,
- category E - healthcare co-workers.

(3) The levels of positions within the categories referred to in paragraph (2) of this Article shall be described by titles, that is, expert or scientific title, where the lowest level in the category is the entry level.

(4) The work experience and the other special requirements that should be met by the person who is to be employed in the public healthcare institution as a healthcare worker, that is, a healthcare co-worker shall be determined by the act on systematization of the public healthcare institution in accordance with the type of required professional qualifications and job competencies, the responsibility, the type and complexity of the works and tasks, as well as in accordance with the other criteria of importance for the job.

Category A - healthcare workers with a higher education in the field of medicine, dentistry and pharmacy

Article 155-b
(1) The following levels of positions of providers of public health services shall be determined within the category A:
- level А1 managerial workers of internal organizational units,
- level А2 doctor of medicine, doctor of dentistry, graduated pharmacist - doctor of sciences - regular professor,
- level А3 doctor of medicine, doctor of dentistry, graduated pharmacist - doctor of sciences - scientific counselor,
- level А4 doctor of medicine, doctor of dentistry, graduated pharmacist - part-time professor,
- level А5 doctor of medicine, doctor of dentistry, graduated pharmacist - doctor of sciences - senior scientific counselor,
- level А6 doctor of medicine, doctor of dentistry, graduated pharmacist - doctor of sciences - scientific associate professor,
- level А7 doctor of medicine, doctor of dentistry, graduated pharmacist - doctor of sciences - scientific associate,
- level А8 doctor of medicine, doctor of dentistry, graduated pharmacist - doctor of sciences - assistant,
- level А9 doctor of medicine, doctor of dentistry, graduated pharmacist - doctor of sciences,
- level А10 doctor of medicine, doctor of dentistry, graduated pharmacist - subspecialist,
- level А11 doctor of medicine, doctor of dentistry, graduated pharmacist - specialist - primarius,
- level А12 doctor of medicine, doctor of dentistry, graduated pharmacist - specialist master of sciences,
- level А13 doctor of medicine, doctor of dentistry, graduated pharmacist - assistant,
- level А14 doctor of medicine, doctor of dentistry, graduated pharmacist - specialist and others,
- level А15 doctor of medicine, doctor of dentistry, graduated pharmacist - primarius,
- level А16 doctor of medicine, doctor of dentistry, graduated pharmacist - master of sciences, and
- level А17 doctor of medicine, doctor of dentistry, graduated pharmacist.

(2) The employees of category A should have at least 240 credits under the ECTS or a completed VII/1 degree.

(3) The employees of category A should hold an internationally recognized certificate issued by an official European tester, a member of ALTE (Association of Language Testers in Europe) or a certificate issued by an international institution for knowledge of one of the three most commonly used languages in the European Union (English, French, German) at A1 level of CEFR, that is, BULATS, or APTIS, or TOEFL PBT at least 310 points, TOEFL CBT at least 35 points or TOEFL IBT at least 10 points or DELF, TCF, TEF, or Goethe-Zertifikat.

(4) As an exception to paragraph (3) of this Article, the person who may be appointed as a head of a unit in a university institute, a university clinic and a clinic in a university clinical center and the persons who are to be employed as healthcare workers with a higher education in a healthcare institution at tertiary level should meet the requirements determined by the provisions of this Law which prescribes the heading with a unit in a university institute, a university clinic and a clinic in a university clinical center and which prescribes the special requirements for employment of healthcare workers with a higher education at tertiary level.

(5) The candidates for a healthcare worker with a higher education who have applied to a public announcement for employment in a public healthcare organization and who hold the internationally recognized certificate for knowledge of one of the three most commonly used languages in the European Union referred to in paragraph (3) of this Article shall be deemed to have passed the qualification examination in the part that refers to examination of knowledge of one of the world languages.

**Category B - healthcare workers with a higher vocational education in the field of medicine and dentistry**

*Article 155-c*
The following levels of positions of providers of public health services shall be determined within the category B - healthcare workers with a higher vocational education in the field of medicine and dentistry:
- level B1 head nurse and head medical technologist at a healthcare institution level, head radiologic technologist, head transfusiologist, head physiotherapeut and others,
- level B2 nurse in charge and medical technologist in charge at an internal organizational unit level, radiologic technologist in charge, transfusiologist in charge, physiotherapeut in charge and others, and
- level B3 graduated nurse and nurse - specialist, graduated radiologic technologist, graduated transfusiologist, graduated speech therapist (integrated studies at the faculty of medicine) and others.

The employees of category B should have at least 180 credits under ECTS.

The employees of category B should hold a certificate for work with office computer programs and a certificate for knowledge of one of the three most commonly used languages in the European Union (English, French, German) at A1 level.

**Category C - healthcare workers with a two-year post-secondary vocational education in the field of medicine and dentistry**

(1) The following levels of positions of providers of public health services shall be determined within the category C - healthcare workers with a two-year post-secondary vocational education in the field of medicine and dentistry:
- level C1n senior healthcare worker specialist in psychiatry, nuclear medicine, dental health prevention, labor medicine, intensive treatment, district nursing, dietetic, communal hygiene, emergency medical care, cast metal technician, transfusiologist, anesthetist, and others and
- level C2n senior sanitary technician, senior dental technician, senior physiotherapeut, senior nurse - midwife, senior medical laboratory technician, transfusiologist, senior pharmacist, senior cytogenetic technician, senior X-ray technician, senior pharmacy technician, dietician, nutritionist, work therapist and others.

(2) The employees of category C should have completed a VI degree of education.

(3) The employees of category C should hold a certificate for work with office computer programs.

**Category D - healthcare workers with a secondary education in the field of medicine, dentistry and pharmacy**

(1) The following levels of positions of providers of public health services shall be determined within the category D - healthcare workers with a secondary education in the field of medicine, dentistry and pharmacy:
- level D1 nurse - instrument nurse, instrument nurse - midwife, nurse - anesthetist, physiotherapeut at reanimation, nurse in intensive care, midwife in birthing room, nurse at dialysis, nurse physiotherapeut and transfusiologist, and others,
- level D2 district nurse, nurse in emergency medical care, home visit nurse, nurse in units of a psychiatric hospital, and others,
- level D3 nurse, midwife, medical technician, dental nurse, medical technologist, medical laboratory technician, pharmacy technician, sanitary technician, physiotherapeut, medical laboratory technician assistant, medical technologist in nuclear medicine, cytogenetic technician, perfusionist, dental technician, radiologic technician, photo laboratory technician, desinsector, dentists, and others,
level D4 health technician for care of the ill, nurse - paramedic and health statistician, and others, and
level D5 general nurse at reception and record room and others.

(2) The employees of category D should have at least secondary vocational education.

(3) The employees of category D should hold a certificate for work with office computer programs.

**Category E - healthcare co-workers**

**Article 155-f**

(1) The following levels of positions of providers of public health services shall be determined within the category E - healthcare co-workers:

- level E1 - healthcare co-workers with specialization and others,
- level E2 - master of science in public health and other masters of science (biologist, physicist, pedagogue, psychologist, speech therapist, surdologist, somatologist) and others,
- level E3 - independent counselor (pedagogue, defectologist, psychologist, speech therapist, biologist, physicist, surdologist, somatologist) and others,
- level E4 graduated engineer, graduated chemist and biochemist, and others,
- level E5 counselor (pedagogue, defectologist, psychologist, speech therapist, biologist, physicist, surdologist, somatologist) and others,
- level E6 graduated pedagogue, graduated defectologist, graduated psychologist, graduated speech therapist, graduated biologist, graduated physicist, graduated surdologist, graduated somatologist, graduated social worker and others, and
- level E7 work therapist, care worker, pedagogue, teacher, senior healthcare associate, engineer in medical radiology, senior social worker and others.

(2) The employees of category E of level E1 to E6 should have at least 240 credits under the ECTS or a completed VII/1 degree of education, and the employees of category E of level E7 should have at least two-year post-secondary education.

(3) The employees of category E, levels E1 to E7 should hold a certificate for work with office computer programs, and the employees of category E, levels E1 to E6 should hold an internationally recognized certificate issued by an official European tester, a member of ALTE (Association of Language Testers in Europe) or a certificate issued by an international institution for knowledge of one of the three most commonly used languages in the European Union (English, French, German) at A1 level of CEFR, that is, BULATS or APTIS, or TOEFL PBT at least 310 points, TOEFL CBT at least 35 points or TOEFL IBT at least 10 points, or DELF, TCF, TEF, or Goethe-Zertifikat.

**Auxiliary-technical persons**

**Article 155-g**

(1) The employees in the public healthcare institutions who carry out auxiliary-technical activities shall have the status of auxiliary-technical persons and the provisions of this Law, the Law on Public Sector Employees, and the general regulations on labor relations shall apply to them.

(2) The following subgroups shall be determined for the auxiliary-technical persons:

- subgroup 1 - auxiliary-technical persons for facility and equipment maintenance,
- subgroup 2 - auxiliary-technical persons for facility and equipment safe-guarding,
- subgroup 3 - auxiliary-technical persons for transport of persons and equipment,
- subgroup 4 - auxiliary-technical persons in a kitchen or hotel and restaurant facility, and
- subgroup 5 - other auxiliary-technical persons.
(3) The following categories and levels shall be determined within the subgroup 1 auxiliary-technical persons for facility and equipment maintenance:
- category A - auxiliary-technical persons for facility maintenance
  - level A1 graduated engineers and others,
  - level A2 engineer (with a degree) and others,
  - level A3 HQ workers (plumber, electrician, fitter, machinist, builder and others) and others, and
  - level A4 Q workers (electrician, technician (TT, TV and others), housekeeper and others, and
- category B - auxiliary-technical persons for equipment maintenance
  - level B1 graduated engineers and others,
  - level B2 engineer (with a degree) and others,
  - level B3 - technician (electro, machine, TT, TV, FF and others) and others, and
  - level B4 - HQ workers (motor mechanic, for steam boiler) and others.

(4) The following categories and levels shall be determined within the subgroup 2 auxiliary-technical persons for facility and equipment safe-guarding:
- category A - auxiliary-technical persons for facility and equipment safe-guarding
  - level A1 guard holding a safeguarding license and others,
  - level A2 fire-fighting technician and others,
  - level A3 fireman and others, and
  - level A4 porter, doorman, and others.

(5) The following categories and levels shall be determined within the subgroup 3 auxiliary-technical persons for transport of persons and equipment:
- category A - auxiliary-technical persons for transport of persons and equipment
  - level A1 ambulance driver and others and
  - level A2 driver and others.

(6) The following categories and levels shall be determined within the subgroup 4 auxiliary-technical persons in a kitchen or hotel and restaurant facility:
- category A - auxiliary-technical persons in a kitchen
  - level A1 HQ worker in a kitchen (cook) and others,
  - level A2 Q server and others, and
  - level A3 server, washer-up in a kitchen and others.

(7) The following categories and levels shall be determined within the subgroup 5 other auxiliary-technical persons:
- category A - hygiene maintenance in the premises,
  - level A1 washer-up in a laboratory, transfusiology, infusion and nuclear medicine and others,
  - level A2 washer, dryer, ironer and others,
  - level A3 cleaning man in healthcare premises and others, and
  - level A4 cleaning man in administrative premises, cleaning man in a kitchen, animal keeper and general workers, washer-up, and others,
- category B - other auxiliary-technical persons
  - level B1 telephonist in a unit and others,
  - level B2 HQ worker - barber and others,
  - level B3 boilerman and others,
  - level B4 MQ workers and others,
  - level B5 Q telephonist and Q workers and others,
  - level B6 Q workers (with passed professional examination) and others,
  - level B7 telephonist in a healthcare institution and workman and others,
  - level B8 workmen and others,
  - level B9 plasterman, material delivery man, and others, and
  - level B10 courier and others.

(8) The employees in the following subgroups, that is, categories and levels should have at least 240 credits under the ECTS or a completed VII/1 degree of education:
- subgroup 1, category A level A1 and
- subgroup 1, category B level B1.

(9) The employees in the following subgroups, that is, categories and levels should have at least 180 credits under the ECTS or a completed VII/1 degree of education:
- subgroup 1, category A level A2 and
- subgroup 1, category B level B2.

(10) The employees in the following subgroups, that is, categories and levels should have at least primary education:
- subgroup 2, category A level A4
- subgroup 4, category A level A3
- subgroup 5, category A level A2 and
- subgroup 5, category B level B3, B7, B8, B9 and B10.

(11) The employees of the rest of the subgroups, that is, categories and levels should have at least a four-years secondary education, that is, a three-year secondary education.

Annual plan for employment of administrative servants, providers of public health services and auxiliary-technical persons

Article 155-h

(1) The director of the public healthcare institution, upon previous opinion from the Ministry of Information Society and Administration and upon previous consent from the Ministry of Health, shall adopt an annual plan for employment of providers of public health services, administrative servants, and auxiliary-technical persons for the following year, in accordance with the Law on Public Sector Employees.

(2) The procedures for filling in vacancies under this Law shall be conducted in accordance with the annual plan referred to in paragraph (1) of this Article and upon a previous notification for provided funds from the Ministry of Finance.

6. Employment of healthcare workers, that is, healthcare co-workers

Employment of healthcare workers, that is, healthcare co-workers

Article 156

The procedure for filling in a vacancy in a healthcare institution shall be regulated in such a manner as the employment of healthcare workers, that is, healthcare co-workers is made in a transparent procedure on the basis of the criteria of expertise and competence and application of the principle of equitable representation of the representatives of the communities.

Manner of filling in a vacancy

Article 157

A vacancy in a healthcare institution shall be filled in by:
- publishing a public announcement for employment,
- publishing an internal announcement for employment,
- assigning a healthcare worker, that is, a healthcare co-worker to another job within the same healthcare institution,
- taking over a healthcare worker, that is, a healthcare co-worker from one to another healthcare institution.

**General and special requirements for employment**

**Article 158**

(1) A person who meets the general and special requirements may be employed in the healthcare institution.

(2) General requirements shall be:
- to be a citizen of the Republic of Macedonia,
- to be of age,
- to be in good general health, and
- not to be imposed a ban on exercising a profession, doing business or performing a function by a legally valid decision.

(3) As an exception to paragraph (2) line 1 of this Article, a healthcare institution may employ a healthcare worker with a university degree who is a foreigner and an established expert in the field of medicine, dental medicine, or pharmacy, following a decision of the Government on the basis of positive opinions of the Ministry of Health and the Ministry of Interior, and in accordance with the regulations on employment of foreigners.

(4) As an exception to paragraph (2) line 1 of this Article, a healthcare institution may also employ a healthcare worker with a university degree who is a foreigner and a citizen of the member states of the European Union, Switzerland, Norway, Canada, Japan, Israel, Turkey, Russia and USA, on the basis of a consent of the Ministry of Health and in line with the regulations on employment of foreigners.

(5) Special requirements shall be:
- to have an adequate level of education,
- to have the required work experience in the profession, and
- other requirements determined by the act on systematization of job.

(6) The healthcare institution may, as a special requirement for employment, determine the candidate to have completed a volunteering period of at least one year in that particular healthcare institution before the entry into force of this Law, as well as to consider the longer period of volunteering as an advantage for employment.

**Public announcement for employment**

**Article 159**

(1) The public announcement for employment in the public healthcare institution shall be published in at least two daily newspapers, one of which is issued in the Macedonian language and one in the language spoken by at least 20% of the citizens who speak an official language other than the Macedonian.

(2) The deadline for applying for the public announcement referred to in paragraph (1) of this Article cannot be shorter than five days as of the day of its publication.

**Candidate selection**

**Article 160**
(1) The managerial body of the health care institution shall form a commission for selection of a healthcare worker, that is, a healthcare co-worker (hereinafter: the selection commission) to conduct the candidate selection procedure.

(2) The candidate for a healthcare worker with a university degree shall be selected on the basis of the following criteria:
1) 40 points for the GPA of the candidate achieved at the higher educational institution and
2) 60 points in total from a qualification examination composed of two parts:
   - an expert part (a test) – 40 points and
   - knowledge of one of the world languages (English, German or French) – 20 points.

(3) The candidates for healthcare workers with secondary education and two-year post secondary education, that is, the healthcare co-workers, shall be selected on the basis of the following criteria:
1) 50 points for the GPA of the candidate achieved in a secondary school, that is, at the higher educational institution and
2) 50 points from the expert part (a test).

(4) The commission for preparation of tests for the expert part and the tests for knowledge of one of the world languages shall be formed by the Ministry of Health and shall include domestic and foreign natural persons and legal entities.

(5) The members of the commission for selection and of the commission for preparation of tests shall sign a statement for keeping confidential the contents of the tests for the expert part and the tests for the knowledge of a world language.

(6) The tests for the expert part and the tests for knowledge of a world language shall be considered as classified information with an appropriate level of secrecy in accordance with the provisions of the Law on Classified Information.

Decision on selection

Article 161

(1) The management body of the healthcare institution shall, based on a ranking list proposed by the selection commission with at least three candidates, provided that there are more than three candidates that meet the requirements, adopt a decision on the selection of a candidate.

(2) The dissatisfied candidate shall have the right to an appeal against the selection decision referred to in paragraph (1) of this Article to the State Commission for Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance, within a period of eight days as of the day of receipt of the decision through the healthcare institution for the needs of which the public announcement was opened.

(3) The body referred to in paragraph (2) of this Article shall decide upon the appeal within a period of 15 days as of the day of receipt of the appeal.

(4) The appeal shall postpone the enforcement of the decision.

(5) The dissatisfied candidate shall have the right to a lawsuit against the decision adopted by the State Commission for Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance before the competent court.

(6) Upon completion of the selection procedure, the management body of the healthcare institution and the selected candidate shall conclude a contract for employment of a healthcare worker, that is, a healthcare co-worker.
**Internal announcement**

**Article 162**

(1) The detailed requirements for applying for an internal announcement in a healthcare institution shall be regulated in a way so that any healthcare worker, that is, healthcare co-worker who meets the general and special requirements of this Law, as well as the following requirements, shall have the right to apply for an internal announcement:
- to have spent at least two years at an immediate lower position than the one for which the internal announcement is opened, and
- not to be imposed a disciplinary measure or a measure for reduced working efficiency within a period of 12 months prior to the opening of the internal announcement.

(2) The internal announcement shall be published on the web location of the healthcare institution.

(3) The provisions on employment by means of a public announcement, except the provision that refers to the opening of a public announcement, shall apply to the employment by means of an internal announcement.

**Reassignment of a healthcare worker, that is, a healthcare co-worker**

**Article 163**

A healthcare worker, that is, a healthcare co-worker who meets the special requirements referred to in Article 158 paragraph (5) of this Law, may be reassigned, according to the needs of the healthcare institution or upon his/her personal request, to another position within the same healthcare institution, in accordance with the act on systematization of jobs.

**Taking over a healthcare worker, that is, a healthcare co-worker**

**Article 164**

A healthcare worker, that is, a healthcare co-worker who meets the special requirements referred to in Article 158 paragraph (6) of this Law, with his/her consent, may be taken over from one to another healthcare institution should the healthcare worker, that is, the healthcare co-worker and the directors, that is, the competent director of the both healthcare institutions agree thereto.

(2) A healthcare worker who carries out a specialist and consultative healthcare activity in a private healthcare institution may be taken over by a public healthcare institution, provided that it has positive financial effects for the public healthcare institution and provided that the healthcare worker, the directors, that is, the competent director of the public healthcare institution by which the worker should be taken over, the Ministry of Health, and the Fund agree thereto.

6-a **Employment of healthcare workers with a higher education at tertiary level**

**Employment of healthcare workers with a higher education at tertiary level**

**Article 164-a**

The procedure for filling in a vacancy in a healthcare institution at tertiary level with healthcare workers with a higher education shall be conducted in accordance with the provisions of this Law.
referring to employment of healthcare workers, unless otherwise determined by the provisions of this chapter.

Special requirements for employment of healthcare workers with a higher education at tertiary level

Article 164-b

(1) Special requirements for employment of healthcare workers with a higher education in the healthcare institution at tertiary level, in addition to the special requirements referred to in Article 158 paragraph (5) of this Law, shall be:
- to have an average achievement in all subjects at all university study cycles completed by the candidate of at least eight (hereinafter: the average achievement) and
- to have active knowledge in one of the three most commonly used languages in the European Union (English, German or French) at B2 level according to the Common European Framework of Reference for Languages: Learning, Teaching, Assessment (hereinafter: CEFR) and to hold an internationally recognized certificate issued by an official European tester, a member of ALTE (Association of Language Testers in Europe) at B2 level of CEFR, that is, IELTS with 5-6 points, FCE, BEC, ILEC, ICFE, BULATS, or APTIS, or TOEFL PBT at least 500 points, TOEFL CBT at least 175 points or TOEFL IBT at least 60 points or DELF, TCF, TEF, or Goethe-Zertifikat, TestDaF.

(2) As an exception, the candidate who has completed specialization or subspecialization which is appropriate for the public healthcare institution at tertiary level wherein the employment procedure is conducted should not meet the special requirement referred to in paragraph (1) line 1 of this Article.

(3) The candidates who have completed the first, the second or the third cycle of studies in medical or dental sciences, that is, pharmacy at one of the top 100 universities under the Shanghai Ranking - ARWU (Academic Ranking of World Universities) should not meet the special requirements referred to in paragraph (1) of this Article nor an employment procedure shall be conducted for their employment.

(4) The knowledge of a foreign language referred to in paragraph (1) of this Article shall be verified by attaching one of the following internationally recognized certificates or internationally used certificates: APTIS, BULATS, CAE, IELTS, FCE, BEC, PET, KET, ILEC, TOEFL PBT, TOEFL CBT, TOEFL IBT for the English language, that is, DELF, DALF, TCF, TEF, BULATS for the French language, that is, Goethe-Zertifikat, TestDaF and BULATS for the German language or another internationally recognized certificate issued by an official European tester, a member of ALTE (Association of Language Testers in Europe) or other international organizations, at B2 level of the Common European Framework of Reference for Languages (CEFR).

(5) The knowledge of a foreign language referred to in paragraph (1) of this Article, in addition to internationally recognized certificates or internationally used certificates, shall be verified by a certificate of a completed first, second or third cycle of studies at one of the top 200 universities under the Shanghai Ranking - ARWU (Academic Ranking of World Universities) in one of the three most commonly used languages of the European Union (English, French, German) for the studies of which the candidate holds a validated diploma.

Selection of a candidate

Article 164-c

(1) The management body of the healthcare institution at tertiary level shall form two commissions for selection of a healthcare worker with a higher education, that is, a commission that shall conduct the written examination and a commission that shall conduct the oral examination within the procedure
for selection of a candidate. The commissions shall be formed by a decision half an hour before holding the written, that is, the oral examination.

(2) The members of the commissions shall be selected by a random choice from among the healthcare workers employed in the healthcare institution where the employment procedure is conducted, who meet the requirements referred to in paragraph (3) of this Article.

(3) The commissions referred to in paragraph (1) of this Article shall be composed of seven members out of which at least two members holding an academic title of a full-time, part-time professor or associate doctor and the rest of the members having specialization, that is, subspecialization, with at least ten years of work experience after the specialization, all in the field in which the candidate is selected.

(4) The selection of the candidate for a healthcare worker with a higher education in a healthcare institution at tertiary level shall be made based on the following criteria:
   1) the achievement at each of the cycles of university studies of the candidate carries 20 points;
   2) the written examination carries 60 points; and
   3) the oral examination carries 20 points.

(5) The achievement of the candidate for a healthcare worker with a higher education in a healthcare institution at tertiary level at all cycles of university studies shall be valued according to the average achievement in all subjects at all cycles of university studies that the candidate has completed and according to the ranking of the university at the ranking list of domestic universities under the Law on Higher Education and the ranking lists of foreign universities, that is: the Shanghai Ranking - ARWU (Academic Ranking of World Universities); the Times Higher Education - World University Rankings, and the QS World University Rankings.

(6) The manner of scoring the candidates based on the achievement at all cycles of university studies of the candidate for a healthcare worker with a higher education in a healthcare institution at tertiary level, the manner of conducting the written and the oral examination, as well as other issued related to the selection procedure, shall be prescribed by the minister of health.

**Taking of an examination**

**Article 164-d**

(1) The written and the oral examination shall be taken in premises for taking an examination, equipped separately for taking an examination with material, technical, and IT equipment, internet connection, and equipment for recording the course of the examination.

(2) The taking of the written and the oral examination shall be recorded and live streamed on the website of the Ministry of Health, and if the recording is interrupted due to technical reasons, the recording of the entire examination shall be posted on the website of the Ministry of Health.

(3) The oral examination shall be public and shall be conducted in the presence of all the candidates, in premises provided by the public healthcare institution that conducts the employment procedure having the capacity necessary for simultaneous presence of all the candidates.

(4) The oral examination shall end by scoring the candidate immediately upon giving the answers at the questions and the candidate shall be informed about the total number of points from the oral examination in the presence of all the candidates in the premises where the examination is conducted, as well as in writing upon the completion of the procedure for selection of a candidate.

(5) The criteria related to the space, and the material, technical and IT equipment in the premises for taking the written and the oral examination shall be laid down by the minister of health.
(6) A representative from the Ministry of Health shall be present in the premises for taking the written and the oral examination.

(7) The database of questions for the written part of the professional examination shall consist of at least 4,000 questions that are reviewed at every two years and that are determined by a commission formed by the minister of health.

(8) The oral examination shall consist of questions that are determined by a commission formed by the minister of health and that are electronically given to the candidate by a random choice right before the beginning of the written examination.

7. Rights and duties of the healthcare workers and the healthcare co-workers

Salary, salary compensations, salary supplement and allowances for work-related costs

Article 165

The healthcare worker, that is, the healthcare co-worker shall be entitled to a salary and salary compensations, salary supplements and allowances for work-related costs under conditions and criteria determined by law, collective agreement and employment contract.

Performance of duties

Article 166

(1) The healthcare worker, that is, the healthcare co-worker shall be obliged to perform the works and the duties conscientiously, professionally, efficiently, duly and timely in accordance with the Constitution, law and ratified international agreements.

(2) The healthcare worker, that is, the healthcare co-worker shall be obliged to do his/her work impartially, not to be guided by his/her personal financial interests, not to abuse the authorizations and the status of a healthcare worker, that is, a healthcare co-worker, and to protect the personal reputation and the reputation of the institution where he/she is employed.

(3) The Doctors’, Dental, that is, Pharmaceutical Chamber shall adopt a Code of Professional Ethical Duties and Rights.

Provision of information and classified information

Article 167

(1) The healthcare worker, that is, the healthcare co-worker shall be obliged, in accordance with the law, to provide information on request of the citizens for the purpose of exercising their rights and interests, except the information referred to in Article 153 of this Law.

(2) The healthcare worker, that is, the healthcare co-worker shall be obliged to keep the classified information in a manner and under conditions determined by law.

(3) The obligation and the time period for keeping the classified information shall be determined in accordance with law.
Consulting services to patients

Article 167-a

The rendering of any type of health or consulting services to patients and/or concluding agreements on rendering health or consulting services to patients with private healthcare institutions by healthcare workers, that is, healthcare co-workers employed in public healthcare institutions shall represent a competitive work and it shall be prohibited.

Engagement of consultants

Article 168

(1) The healthcare workers and the healthcare co-workers may be consultants and advisors, individually or in a group, and provide services as orators or chairmen at meetings, participate in medical/scientific studies, clinical trials or provide training services, participate in advisory meetings and participate in market research, where such participation includes remuneration and/or traveling.

(2) The relationships between the healthcare workers and the healthcare co-workers with the parties ordering the services referred to in paragraph (1) of this Article shall be mandatorily regulated in advance by a written agreement particularly regulating:
- the description of the services and the basis for their payment;
- the clear identification of the justified need of such type of services by consultants and/or advisors;
- the clearly defined criteria on the basis of which the consultants or the advisors are to be selected and their direct connection with the identified need and the persons who are to be responsible for selection of consultants and/or advisors;
- the explanation of the necessity to engage the number of consultants or advisors, adequate to the aim to be achieved;
- the amount of the fee for the service which corresponds to the market value of the provided service;
- the obligation of the party ordering the services to keep records of the provided services by the healthcare workers and the healthcare co-workers, and
- the obligation of the healthcare worker and the healthcare co-worker to present the information that he/she is a consultant and/or advisor of the party ordering the service when speaking to the public or writing about a matter which is the subject matter of the agreement or about any other matter concerning the party ordering the service.

(3) The rendering of consulting services to patients by healthcare workers, that is, the healthcare co-workers employed in a public healthcare institution outside the healthcare institution in which they are employed shall be prohibited.

Tags

Article 169

The healthcare worker, that is, the healthcare co-worker who works with clients shall be obliged, during the working hours, at his/her workplace, to wear a tag in a visible place containing the name, the position and the healthcare institution where he/she works.

Professional training and development

Article 170
(1) The healthcare worker, that is, the healthcare co-worker shall have the right and duty to take professional training and development in accordance with the needs of the healthcare institution in which he/she is employed.

(2) The healthcare worker, that is, co-worker may receive a donation or sponsorship for participation in professional gatherings, seminars, workshops and alike from natural persons or legal entities, in order to take additional training and development.

(3) The Ministry of Health shall grant a prior consent for the donation and the sponsorship referred to in paragraph (2) of this Article.

(4) The donations and the sponsorships referred to in paragraph (2) of this Article shall be ex officio entered in the register of sponsorships and donations by the Ministry of Health.

(5) The register of sponsorships and donations shall be kept by the Ministry of Health under the conditions determined by this Law and the Rulebook on Registration of Consents for Sponsorships and Donations, adopted by the minister of health.

(6) The Rulebook referred to in paragraph (5) of this Article shall regulate the manner of entry, the contents, the electronic keeping of the register, and the other matters relevant for the register to be duly kept.

**Presentation of a new healthcare method or procedure, that is, knowledge, capacities and skills gained during the professional training and/or professional development abroad**

**Article 170-a**

(1) The healthcare worker, that is, the healthcare co-worker employed in a public healthcare institution who has attended a professional training and/or professional development abroad shall be obliged, within a period of two weeks as of the day of return from the professional training and/or professional development, to make a presentation of the new healthcare method or procedure, that is, of the knowledge, capacities and skills gained during the professional training and/or professional development before the professional collegium.

(2) The presentation referred to in paragraph (1) of this Article shall be recorded and shall be posted on the website of the Ministry of Health within 24 hours as of the making of the presentation and it shall be kept there for at least five years.

(3) The healthcare worker, that is, the healthcare co-worker who does not act in accordance with paragraph (1) of this Article shall be obliged to return the funds paid for his/her professional training and/or professional development abroad to the Ministry of Health, that is, to the public healthcare institution within a period of one month as of the return from the professional training and/or professional development.

**Right to protection**

**Article 171**

(1) The healthcare worker, that is, the healthcare co-worker and the members of his/her immediate family shall be entitled to protection if he/she is directly threatened, attacked or suffers similar actions related to the provision of health services.
(2) The healthcare institution where the healthcare worker, that is, the healthcare co-worker works shall be obliged to ensure protection to the healthcare worker, that is, the healthcare co-worker in the cases referred to in paragraph (1) of this Article.

**Right to associate in a union**

**Article 172**

For the purpose of exercising the economic and social rights, the healthcare workers, that is, the healthcare co-workers shall have the right to form unions and to be members therein under the conditions and in a manner determined by law.

**Right to strike**

**Article 173**

The healthcare workers, that is, the healthcare co-workers shall have the right to a strike, organized in accordance with law.

**Participation in an electoral process**

**Article 174**

(1) The healthcare workers, that is, the healthcare co-workers shall be obliged to participate in the electoral process as members of an electoral body, provided that they are selected by a competent electoral body.

(2) The healthcare workers, that is, the healthcare co-workers who are selected for members of an electoral body may not accept to carry out the duty only because of health and family reasons established by the electoral body which has selected them on the basis of the appropriate documentation submitted.

**Membership in a political party**

**Article 175**

(1) The healthcare worker, that is, the healthcare co-worker must not endanger the performance of the works and the duties deriving from the status of a healthcare worker, that is, a healthcare co-worker by being a member in a political party and by participating in its activities.

(2) The healthcare worker, that is, the healthcare co-worker must not wear or point out party symbols in the work premises.

**Right to a rest period and leaves of absence from work**

**Article 176**

The healthcare worker, that is, the healthcare co-worker shall have the right to a rest period and leaves of absence from work in accordance with the labor relation regulations.

**Inability to come to work**
Article 177

In the case the healthcare worker, that is, the healthcare co-worker is not able to come to work, he/she shall be obliged to notify the immediate superior healthcare worker, that is, healthcare co-worker within a period of 24 hours as of the moment of inability. If that is not possible to be done due to objective reasons or force majeure, in that case the healthcare worker, that is, the healthcare co-worker shall be obliged to do so immediately after the termination of the reason which has made the notification not possible.

Employment in abeyance

Article 178

The employment of a healthcare worker, that is, a healthcare co-worker who is elected or appointed to a state or public office determined by law, the execution of which requires temporary suspension of the execution of the works and the duties as a healthcare worker, that is, a healthcare co-worker, shall be held in abeyance, and he/she shall have the right, within a period of 15 days following the termination of the execution of the office, to return to the healthcare institution wherefrom he/she has left to execute the office to a position which corresponds to his/her level of professional training.

Return to work

Article 179

(1) The employment of the healthcare worker, that is, the healthcare co-worker who is posted to work abroad under international and technical or educational and cultural and scientific cooperation, in diplomatic and consular offices, shall be held in abeyance and he/she shall have the right, within a period of 15 days as of the day of termination of the work abroad, to return to the healthcare institution wherefrom he/she has left abroad to a position that corresponds to his/her level of professional training.

(2) The employment of the healthcare worker, that is, the healthcare co-worker whose spouse is posted to work abroad under international and technical or educational and cultural and scientific cooperation, in diplomatic and consular offices, shall be held in abeyance upon his/her personal request, and he/she shall have the right, within a period of 15 days as of the day of termination of the work of his/her spouse abroad, to return to the healthcare institution wherefrom he/she has left abroad to a position that corresponds to his/her level of professional training.

7-a. Special rights and duties of healthcare workers with a higher education in the field of medicine employed in public healthcare institutions at tertiary level

Period of monitoring

Article 179-a

(1) A healthcare worker with a completed higher education in the field of medical or dental sciences, that is, pharmacy, employed in a public healthcare institution which carries out a healthcare activity at tertiary level (hereinafter: doctor of medicine, doctor of dentistry or pharmacists at tertiary level) shall have the right and duty to adopt and use all the healthcare methods and/or procedures for improvement of the health, the diagnostics and the treatment of diseases, injuries and the rehabilitation that are used in the public healthcare institution where he/she is employed (hereinafter: existing healthcare methods and/or procedures), within a period of two years as of the day of employment as a doctor of medicine, specialist, that is, subspecialist, that is, as a doctor of dentistry,
specialist, that is, subspecialist, and as a pharmacist, specialist, that is, subspecialist. The doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level shall have the right and duty, within the same period, to improve and independently use the existing healthcare methods and procedures that are used in the unit where he/she works (hereinafter: period of monitoring).

(2) The doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level cannot be reassigned to another internal organizational unit within the period referred to in paragraph (1) of this Article.

(3) The doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level shall be obliged, during the period of monitoring, in 30% of the cases in which he/she, as a doctor of medicine, a doctor of dentistry or a pharmacist at tertiary level, participates in the use of the existing healthcare method or procedure, to apply the method or the procedure independently, under surveillance of the specialist, that is, subspecialist who applies the respective existing healthcare methods and procedures (internal educator), which is recorded in the basic medical documentation.

(4) The adoption and the improvement of the healthcare methods and procedures referred to in paragraph (1) of this Article shall be monitored by the head of the internal organizational unit where the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level works (hereinafter: mentor during the period of monitoring) and shall be confirmed by the specialist, that is, the subspecialist who applies the respective healthcare methods and procedures (internal educator) for which records of evaluation are kept and which are an integral part of the personal file of the doctor of medicine.

(5) The form and the contents of the records of evaluation referred to in paragraph (4) of this Article shall be determined by the minister of health.

(6) The doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level shall be issued a certificate for successfully completed period of monitoring based on a report prepared by the head of the internal organizational unit where the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level works, which assesses the success by taking into consideration the duty referred to in paragraph (3) of this Article, as well as the number of repeated hospitalizations with the same diagnosis within a period of 30 days as of the day of discharging from the hospital, and the number of repetitions of the method or the procedure during the hospital treatment in all the cases where the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level independently applies an existing healthcare method and/or procedure.

(7) The director of the public healthcare institution at tertiary level shall be obliged to establish records of the existing healthcare methods and procedures that are used in the public healthcare institution managed by him/her.

(8) The form and the contents of the records referred to in paragraph (7) of this Article shall be determined by the minister of health.

(9) If the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level, during the period of monitoring, does not adopt or improve successfully the healthcare methods and procedures that are used in the unit where he/she works, he/she shall be transferred by force of law to a public healthcare institution that carries out a healthcare activity at secondary level.

(10) The director of the public healthcare institution at tertiary level shall be obliged to notify the Ministry of Health within a period of 30 days as of the expiry of the period of monitoring that the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level has not adopted and improved successfully the healthcare methods and procedures during the period of monitoring.

(11) The Ministry of Health, in the case referred to in paragraph (9) of this Article, shall be obliged to offer the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level employment in
a public healthcare institution that carries out a healthcare activity at secondary level by transferring and concluding an employment contract for carrying out activities that correspond to his/her professional training. The employment contract shall be concluded between the public healthcare institution which carries out a healthcare activity at secondary level and the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level, upon previously obtained consent from the Ministry of Health.

(12) If the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level does not agree to be transferred and does not conclude the employment contract in accordance with paragraph (11) of this Article, his/her employment shall terminate by force of law.

**Period for introduction of a new healthcare method and/or procedure**

**Article 179-b**

(1) For the purpose of raising the level of health protection, the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level shall have the right and duty, upon the expiry of the period of monitoring referred to in Article 179-a paragraph (1) of this Law, to introduce and to start to independently use, every seven years, at least one new healthcare method or procedure approved in accordance with Article 17 paragraph (8) of this Law which has not been used in the public healthcare institution where he/she is employed until then (hereinafter: period for introduction of a new healthcare method and/or procedure).

(2) A healthcare method or procedure that the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level has introduced as a new in a public healthcare institution that carries out a healthcare activity in the network at secondary level where such a healthcare method or procedure has not been used until then or has trained at least one doctor, one doctor of dentistry or one pharmacist employed in that public healthcare institution for its independent use, without his/her participation, which is verified by a certificate issued by the healthcare institution shall be also deemed a new healthcare method or procedure.

(3) Upon approval, that is, introduction of the new healthcare method or procedure referred to in paragraphs (1) and (2) of this Article, the directors of the public healthcare institution where the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level is employed shall be obliged to provide the necessary conditions (space and/or equipment) for introduction and use of the new healthcare method or procedure.

(4) Within the period of seven years for introduction of a new healthcare method and/or procedure, the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level shall have the right and duty to spend at least one year in total in professional development abroad in accordance with the regulations on medical studies and continuous professional development of the doctors of medicine which the public healthcare institutions shall be obliged to plan in the annual plans for training of the doctors of medicine, specialists and subspecialists abroad, and the Ministry of Health shall be obliged to plan them in the annual programs for training of doctors of medicine, specialists and subspecialists.

(5) If the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level in the period for introduction of a new healthcare method or procedure does not introduce at least one new healthcare method or procedure or does not spend at least one year in total in professional development abroad in accordance with paragraph (4) of this Article, he/she shall be transferred by force of law in a public healthcare institution that carries out a healthcare activity at secondary level.

(6) The director of the public healthcare institution at tertiary level shall be obliged to inform the Ministry of Health within a period of 30 days as of the expiry of the period for introduction of a new healthcare method or procedure that the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level has not introduced at least one new healthcare method or procedure within the period
for introduction of a new healthcare method or procedure or has not spent at least one year in total in professional development abroad in accordance with paragraph (4) of this Article.

(7) The Ministry of Health, in the case referred to in paragraph (6) of this Article, shall be obliged to offer the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level employment in a public healthcare institution that carries out a healthcare activity at secondary level by transferring and concluding an employment contract for carrying out activities that correspond to his/her professional training. The employment contract shall be concluded between the public healthcare institution which carries out a healthcare activity at secondary level and the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level, upon previously obtained consent from the Ministry of Health.

(8) If the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level does not agree to be transferred and does not conclude the employment contract in accordance with paragraph (7) of this Article, his/her employment shall terminate by force of law.

**Period for publication of a paper or participation in scientific research projects**

**Article 179-c**

(1) The doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level shall be obliged to publish at least one paper in a scientific journal having an impact factor or to be a holder or a coordinator of a national, regional or international scientific research project at every ten years upon the expiry of the period of monitoring referred to in Article 179-a paragraph (1) of this Law. The costs for publication of the papers in a scientific journal having an impact factor shall be covered by the Program for Education of Doctors of the Ministry of Health.

(2) If the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level does not publish at least one paper in a scientific journal having an impact factor within the period of ten years determined in paragraph (1) of this Article or is not a holder or coordinator of a national, regional or international scientific research project, he/she shall be transferred in a public healthcare institution carrying out a healthcare activity at secondary level by force of law.

(3) The director of the public healthcare institution at tertiary level shall be obliged to inform the Ministry of Health, within a period of 30 days as of the expiry of the period of ten years determined in paragraph (1) of this Article, that the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level has not publish at least one paper in a scientific journal having an impact factor within the period of ten years determined in paragraph (1) of this Article or has not been a holder or coordinator of a national, regional or international scientific research project.

(4) The Ministry of Health, in the case referred to in paragraph (3) of this Article, shall be obliged to offer the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level employment in a public healthcare institution that carries out a healthcare activity at secondary level by transferring and concluding an employment contract for carrying out activities that correspond to his/her professional training. The employment contract shall be concluded between the public healthcare institution which carries out a healthcare activity at secondary level and the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level, upon previously obtained consent from the Ministry of Health.

(5) If the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level does not agree to be transferred and does not conclude the employment contract in accordance with paragraph (4) of this Article, his/her employment shall terminate by force of law.

**8. Liability of healthcare workers, that is, healthcare co-workers**
Personal liability

Article 180

The healthcare worker, that is, the healthcare co-worker shall be personally liable for the performance of the works and the duties deriving from the job.

Disciplinary liability

Article 181

(1) The manner and procedure for establishing disciplinary liability in a healthcare institution shall be regulated in a manner that the healthcare worker, that is, the healthcare co-worker shall be held disciplinary liable for violation of the working discipline, non-performance, unconscientious, and untimely performance of the works and duties.

(2) The liability for a committed crime, that is, a misdemeanor shall not exclude the disciplinary liability of the healthcare worker, that is, the healthcare co-worker.

Disciplinary irregularity and disciplinary offense

Article 182

(1) The healthcare worker, that is, the healthcare co-worker shall be held disciplinary liable for both disciplinary irregularity and disciplinary offense.

(2) Disciplinary irregularity, in terms of paragraph (1) of this Article, shall be a minor violation of the work discipline, non-performance, unconscientious, and untimely performance of the works and duties.

(3) Disciplinary offense, in terms of paragraph (1) of this Article, shall be a more severe violation of the work discipline, non-performance, unconscientious, and untimely performance of the works and duties.

Disciplinary measures

Article 183

(1) In the case of disciplinary irregularity or disciplinary offense, the healthcare worker, that is, the healthcare co-worker may, by a decision, be imposed one of the following disciplinary measures:
1) public reprimand;
2) fine in the amount of 20% to 30% of the one-month amount of the net salary paid for the month that precedes the commission of the violation in the provision of the health service, in duration of one to six months; and
3) termination of employment.

(2) The severity of the disciplinary irregularity or offense, their consequences, the degree of liability of the healthcare worker, that is, the healthcare co-worker, the circumstances under which the disciplinary irregularity or offense is committed, his/her previous conduct and performance of the works and duties, as well as other mitigating and aggravating circumstances shall be taken into consideration when imposing the disciplinary measures referred to in paragraph (1) of this Article.

Disciplinary irregularity
Article 184

(1) Disciplinary irregularity shall be:
1) non-observance of the working hours, the schedule and the use of the working hours despite the reprimand of the immediate superior healthcare worker, that is, healthcare co-worker;
2) unjustified absence from work up to two working days during one calendar year;
3) not wearing the tags referred to in Article 169 of this Law;
4) non-performance or unconscientious, untimely, inappropriate or negligent performance of the works and duties having less serious consequences of the violation;
5) not informing the immediate superior healthcare worker, that is, healthcare co-worker, that is, managerial person of the healthcare institution regarding the inability to come to work within a period of 24 hours due to unjustified reasons;
6) refusal of professional training and development to which the healthcare worker, that is, the healthcare co-worker is referred; and
7) carrying out of the works and duties at a lowered level of performance.

(2) A public reprimand or a fine in the amount of 20% of the one-month amount of the net salary paid in the month that precedes the commission of the disciplinary irregularity may be imposed for a disciplinary irregularity in duration of one to three months.

Imposition of disciplinary measures for disciplinary irregularity

Article 185

(1) The disciplinary measures against the healthcare worker, that is, the healthcare co-worker for a disciplinary irregularity shall be imposed by the management body, upon a prior written report of the immediate superior healthcare worker, that is, healthcare co-worker.

(2) In the case of obvious disciplinary irregularity, the management body shall impose a disciplinary measure even without a prior written report of the immediate superior healthcare worker, that is, healthcare co-worker.

(3) Before imposing the disciplinary measure, the healthcare worker, that is, the healthcare co-worker shall be informed in writing about the allegations in the report referred to in paragraph (1) of this Article against him/her and he/she shall have the right to deliver an oral or written response within a period that cannot be shorter than five days.

(4) The management body of the healthcare institution shall adopt a decision imposing a disciplinary measure for a disciplinary irregularity within a period of 30 days as of the initiation of the procedure.

Disciplinary offense

Article 186

(1) Disciplinary offense shall be:
1) non-performance or unconscientious, untimely, inappropriate or negligent performance of the works and duties;
2) wearing or placing party symbols in the work premises;
3) refusing to give or giving false data to the state bodies, the legal entities and the citizens, if the giving of data is prescribed by law;
4) unlawful management of funds;
5) refusing to perform the works and duties of the job to which he/she is assigned or refusing orders from the management body of the healthcare institution;
6) not taking or partially taking the prescribed security measures for protection of the entrusted assets;
7) causing greater material damage;
8) repeating a disciplinary irregularity;
9) receiving gifts or other type of benefits contrary to the law, or receiving or accepting an offer to receive a gift, money or any other type of benefit in order to recommend, prescribe or procure particular medicaments;
10) abusing the status or exceeding the authorizations in the performance of the activities;
11) abusing the sick leave;
12) disclosing classified information with a degree of secrecy determined in accordance with law;
13) taking in, using, and working under the influence of alcohol or narcotics;
14) non-complying with the regulations on disease protection, safety at work, protection against fire, explosion, harmful influence of poisons and other hazardous substances and violation of the regulations on environmental protection;
15) posing the personal financial interest in conflict with the position and the status of a healthcare worker, that is, a healthcare co-worker;
16) behaving offensively or violently;
17) unjustifiably refusing to participate in electoral bodies; and
18) obstructing the elections and voting, violation of the electoral right, violation of the voters’ freedom of choice, electoral bribery, violation of the secrecy of voting, destruction of electoral documents, electoral fraud committed by a healthcare worker, that is, a healthcare co-worker as a member of the electoral body.

(2) The following disciplinary measure shall be imposed for the disciplinary offenses referred to in paragraph (1) of this Article:
- fine in the amount of 20% to 30% of the one-month net salary paid to the healthcare worker, that is, the healthcare co-worker in the month that precedes the commission of the disciplinary offense, in duration of one to six months and
- termination of the employment if there are harmful consequences for the healthcare institution and if, in the disciplinary procedure, no mitigating circumstances have been found for the healthcare worker, that is, the healthcare co-worker who has committed the offense.

**Disciplinary procedure commission**

**Article 187**

(1) The management body of the healthcare institution shall form a commission for conducting the disciplinary procedure for a disciplinary offense.

(2) The commission referred to in paragraph (1) of this Article shall be composed of a president and two members one of whom is a representative of the union, and their deputies.

(3) The principle of equitable representation of all the communities in the Republic of Macedonia shall apply to the forming of the commission referred to in paragraph (1) of this Article.

**Decision on imposition of a disciplinary measure**

**Article 188**

The management body of the healthcare institution shall adopt a decision on imposition of a disciplinary measure for a disciplinary offense within a period of 60 days as of the day of commencement of the procedure, on the basis of a proposal of the commission referred to in Article 187 paragraph (1) of this Law.

**Subjective deadline for initiation of a disciplinary procedure**

**Article 189**
The disciplinary procedure cannot be initiated if six months have passed as of the day the immediately superior healthcare worker, that is, healthcare co-worker, that is, management body of the healthcare institution has found out about the violation of the working discipline, non-performance, unconscientious and untimely performance of the works and duties.

**Objective deadline for initiation of a disciplinary procedure**

**Article 190**

The disciplinary procedure cannot be initiated if 12 months have passed as of the day of commission of the violation of the working discipline, non-performance, unconscientious and untimely performance of the works and duties.

**Absolute deadline for initiation of a disciplinary procedure**

**Article 191**

If the violation of the working discipline, non-performance, unconscientious and untimely performance of the works and duties also implies criminal liability, the disciplinary procedure for establishment of the liability of the healthcare worker, that is, the healthcare co-worker cannot be initiated if two years have passed as of the day of finding out about the violation.

**Temporary suspension**

**Article 192**

(1) The healthcare worker, that is, the healthcare co-worker may be temporarily suspended from the healthcare institution on the basis of a decision of the management body of the healthcare institution.

(2) The healthcare worker, that is, the healthcare co-worker may be temporarily suspended from the healthcare institution in the cases where a criminal procedure is initiated against him/her for a crime committed at work or in relation with the work, where a criminal procedure is initiated against him/her for a crime prosecuted ex officio and for which an imprisonment sentence of more than five years is foreseen, or a disciplinary procedure is initiated for a disciplinary offence and the nature of the violation or of the omission of actions are such that his/her further presence in the healthcare institution, in the course of the procedure, would harmfully reflect on the healthcare activity, that is, it would foil or obstruct the establishment of the liability for the disciplinary offence.

(3) The suspension referred to in paragraph (2) of this Article shall last until the adoption of a final decision in the disciplinary procedure.

(4) During the temporary suspension of the healthcare worker, that is, the healthcare co-worker, he/she shall be entitled to a salary in the amount of 50% of the salary received in the previous month.

**Right to appeal**

**Article 193**

(1) The healthcare worker, that is, the healthcare co-worker shall have the right to file an appeal against the decision on imposing a disciplinary measure and temporary suspension within a period of eight days as of the day of receipt of the decision through the healthcare institution to the State Commission on Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance.
(2) The body referred to in paragraph (1) of this Article shall decide upon the appeal within a period of eight days as of the day of receipt of the appeal.

Material liability

Article 194

(1) The healthcare worker, that is, the healthcare co-worker shall be liable for the damage he/she has caused at work or in relation with the work in the healthcare institution, intentionally or due to excessive negligence.

(2) The management body of the healthcare institution shall form a commission for establishment of the material liability of the healthcare worker, that is, the healthcare co-worker.

(3) The commission referred to in paragraph (2) of this Article shall be composed of a president and two members, one of whom is a representative of the union, and their deputies.

Decision on damage compensation

Article 195

(1) The management body of the institution shall adopt a decision on damage compensation within a period of 60 days as of the day of commencement of the procedure.

(2) The healthcare worker, that is, the healthcare co-worker shall have the right to file an appeal against the decision referred to in paragraph (1) of this Article within a period of eight days as of the day of receipt of the decision through the healthcare institution to the State Commission for Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance.

Subjective deadline for initiation of a procedure

Article 196

The procedure for establishment of the material liability cannot be initiated if 60 days have passed as of the day the immediate superior healthcare worker, that is, healthcare co-worker or the management body of the institution have found out about it.

Objective deadline for initiation of a procedure

Article 197

The procedure for establishment of the material liability cannot be initiated if a year has passed as of the day of causing the material damage.

Initiation of a court procedure

Article 198

If the healthcare worker, that is, the healthcare co-worker fails to compensate the damage within a period of three months after the decision on damage compensation becomes final, the healthcare institution shall initiate a procedure before the competent court.
Compensation for damage caused at work

Article 199

If a healthcare worker, that is, a healthcare co-worker suffers damage at work or in relation with the work, the healthcare institution shall be obliged to compensate the damage in accordance with law.

Annual report

Article 200

(1) The institution shall be obliged to submit an annual report on the measures imposed for the established disciplinary and material liability of the healthcare workers, that is, the healthcare co-workers to the Agency for Administration no later than 31 January in the current year for the preceding year.

(2) The contents and the form of the report referred to in paragraph (1) of this Article shall be prescribed by an act of the minister of health.

9. Termination of employment of healthcare workers, that is, healthcare co-workers

Termination of employment

Article 201

The employment of the healthcare worker, that is, the healthcare co-worker shall terminate:
- by agreement,
- at his/her own request,
- by force of law, and
- in other cases determined by this Law.

Termination of employment by agreement

Article 202

The employment of the healthcare worker, that is, the healthcare co-worker shall terminate by an agreement upon conclusion of a written agreement for termination of the employment with the management body of the healthcare institution.

Procedure for termination of employment by agreement

Article 203

(1) The employment of the healthcare worker, that is, the healthcare co-worker shall terminate if he/she submits a written request for termination of the employment.

(2) In the case of termination of the employment upon a request of the healthcare worker, that is, the healthcare co-worker, the notice period shall be 30 days as of the day of submission of the request for termination of the employment, unless the healthcare worker, that is, the healthcare co-worker and the management body of the healthcare institution agree otherwise.
(3) In the cases of filing a written request for termination of the employment, the employment of the healthcare worker, that is, the healthcare co-worker shall not terminate until the return of the funds referred to in Article 147 paragraph (3) of this Law.

**Termination of employment by force of law**

**Article 204**

The employment of the healthcare worker, that is, the healthcare co-worker shall terminate by force of law if:
- he/she loses the working ability – as of the day of submission of the legally valid decision on establishment of the lost working ability,
- his/her citizenship of the Republic of Macedonia terminates – as of the day of submission of the decision on renunciation of citizenship of the Republic of Macedonia,
- he/she has been imposed a prohibition to practice profession, perform activity or duty – as of the day the decision becomes legally valid,
- he/she is convicted of a crime with regard to the official duty or another crime that makes him/her indecent for a healthcare worker, that is, a healthcare co-worker and for carrying out the duty in the healthcare institution – as of the day of handing over the legally valid verdict,
- he/she serves a prison sentence of more than six months – as of the first day of serving the sentence,
- his/her employment contract or the extended employment contract terminates for the reason of age in accordance with the regulations in the field of labor relations,
- the doctor of medicine, the doctor of dentistry or the pharmacist at tertiary level does not agree to be transferred and does not conclude the contract for employment in a public healthcare institution that carries out a healthcare activity at secondary level in accordance with Articles 179-a paragraph (11), 179-b paragraph (7), and 179-c paragraph (4) of this Law.

**Other cases of termination of employment**

**Article 205**

The employment of the healthcare worker, that is, the healthcare co-worker shall also terminate in the cases if:
- he/she is unjustifiably absent from work at least three working days in a row or five working days during one year,
- it is established that, in the course of the employment procedure, he/she has concealed or has given false data concerning the general and specific requirements for employment,
- upon a request of the management body of the healthcare institution, the healthcare worker, that is, the healthcare co-worker does not perform the duties determined in the job description, although he/she has been provided the necessary conditions, instructions and directions for work, and has been previously warned in writing that there is dissatisfaction with the manner of performing the duties and he/she has been given a deadline, not longer than 30 days, to improve his/her work,
- it is determined that the healthcare worker, that is, the healthcare co-worker is performing an additional activity contrary to the provisions of this Law, and it is determined that the healthcare worker, that is, the healthcare co-worker employed in a public healthcare institution gives consulting services to patients outside the healthcare institution in which he/she is employed,
- it is determined that he/she has acted contrary to Article 39-a paragraph (3) of this Law, for the second time,
- he/she, within a period of five days, does not return to work after the completion of the professional training or development, and he/she, within a period of five days, does not return to work after the completion of the professional training or development, and
- the state administrative body responsible for labor inspection establishes that the healthcare worker, that is, the healthcare co-worker is employed contrary to the provisions of this and another law.
Decision on termination of employment of a healthcare worker, that is, a healthcare co-worker

**Article 206**

(1) The decision on termination of employment of the healthcare worker, that is, the healthcare co-worker shall be adopted by the management body of the healthcare institution.

(2) The decision on termination of employment shall be handed in person to the healthcare worker, that is, the healthcare co-worker as a rule at the business premises of the healthcare institution where the healthcare worker, that is, the healthcare co-worker works, that is, at the address of his/her permanent residence, that is, temporary residence wherefrom the healthcare worker, that is, the healthcare co-worker comes to work every day.

(3) If the healthcare worker, that is, the healthcare co-worker cannot be found at the address of his/her permanent residence, that is, temporary residence or if he/she rejects to receive the decision, the decision shall be posted on the notice board in the healthcare institution. Following the expiry of three working days, it shall be considered that the decision is handed over.

**Appeal**

**Article 207**

(1) The healthcare worker, that is, the healthcare co-worker shall have the right to file an appeal against the decision on termination of employment within a period of eight days as of the day of receipt of the decision through the healthcare institution to the State Commission for Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance.

(2) The decision upon the appeal shall be adopted by the body deciding in second instance within a period of 15 days as of the day of receipt of the appeal.

(3) The appeal shall postpone the enforcement of the decision on termination of employment until the adoption of the final decision upon the appeal.

10. Protection and decision-making upon the rights and obligations of the healthcare workers, that is, the healthcare co-workers

**Right to appeal**

**Article 208**

(1) The healthcare worker, that is, the healthcare co-worker whose employment right is violated by a decision of the healthcare institution, shall have the right to file an appeal to the State Commission for Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance through the healthcare institution which has adopted the first instance decision within a period of eight days as of the day of receipt of the decision.

(2) The healthcare institution referred to in paragraph (1) of this Article shall be obliged to submit the appeal, along with the attached documents, to the State Commission for Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance, within a period of eight days as of the day of receipt of the appeal.
(3) The State Commission for Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance shall adopt a decision upon the filed appeal referred to in paragraph (1) of this Article within a period of 15 days as of the day of receipt of the appeal.

**Right to court protection**

**Article 209**

(1) The healthcare worker, that is, the healthcare co-worker who is not satisfied with the final decision adopted by the State Commission for Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance shall have the right to request protection of his/her rights before the competent court within the subsequent deadline of 15 days.

(2) The healthcare worker, that is, the healthcare co-worker cannot request protection of the right before a competent court if he/she has not previously sought protection of the right before the State Commission for Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance, except for the right to monetary compensation.

**11. Rights and obligations of employees in healthcare institutions who are not healthcare workers, that is, healthcare co-workers**

**Rights and obligations of administrative servants and auxiliary-technical persons in public healthcare institutions**

**Article 210**

(1) The employees in the public healthcare institutions who carry out administrative activities shall have the status of administrative servants.

(2) The provisions of the Law on Administrative Servants and the general regulations on labor relation shall apply to the issues related to the employment of the employees referred to in paragraph (1) of this Article, but are not regulated by this Law and the collective agreement.

(3) The employees in the public healthcare institutions who carry out auxiliary and technical activities shall have the status of auxiliary-technical persons.

(4) The provisions of the Law on Public Sector Employees and the general regulations on labor relations shall apply to the auxiliary-technical persons in the public healthcare institutions.

**VIII. ORGANIZATION OF THE WORK IN THE HEALTHCARE INSTITUTIONS IN THE NETWORK**

**Obligation for continuous carrying out of a healthcare activity**

**Article 211**

(1) The healthcare institutions in the network shall be obliged to ensure continuous carrying out of the healthcare activity, organized in one, two, three or more shifts, as work in the mornings and afternoons, by changing the working hours, readiness or on-duty work, in accordance with the needs of the population and the forms of rendering health services.
(2) As an exception to paragraph (1) of this Article, the healthcare institutions at primary level may also organize the performance of the healthcare activity in two other populated places with less than 1,000 inhabitants at the most and at least twice a week, if they meet the requirements referred to in Article 60 paragraph (1) point 3 of this Law.

(3) For the purpose of better organization and increased utilization of the space and equipment for work, as well as for better organization in the performance of the healthcare activity, the working hours shall be organized in shifts in a manner set out by the regulations in the field of labor relations.

(4) The healthcare worker cannot leave his/her work place even after the end of the working hours until his/her shift arrives, provided that it poses a risk to the patients’ health.

(5) The continuous carrying out of the healthcare activity shall be ensured by on-duty work only if there is no other way to ensure continuous carrying out of the healthcare activity.

(6) In case of a need of ensuring continuous carrying out of a healthcare activity by on-duty work, the healthcare institution in the network shall be obliged to provide consent from the Ministry of Health, and in the case where the provision of continuous carrying out of a healthcare activity is not provided by on-duty work, and a need arises, the healthcare institution in the network shall be obliged to previously notify the Ministry of Health about the reasons and the duration of such need.

**Manner of organization of the work and ensuring continuous carrying out of the healthcare activity**

**Article 212**

(1) The roster, the beginning and the end of the working hours of the public healthcare institutions in the network shall be prescribed by the minister of health, depending on the type and scope of healthcare activity that needs to be harmonized with the needs of the citizens, in order to provide the citizens with continuous use of health protection services.

(2) The manner of organizing the work and the continuous carrying out of the healthcare activity through on-duty work, in line with the needs of the citizens and the type and scope of the health protection, shall be prescribed by the minister of health.

(3) If the continuous carrying out of the healthcare activity in a public healthcare institution is not possible due to lack of personnel, the public healthcare institutions may conclude a mutual agreement on provision of health services aimed at provision of continuous use of health protection services, upon a previously established need and a previous consent of the minister of health.

(4) The agreement referred to in paragraph (3) of this Article shall regulate the rights and obligations of the public healthcare institutions, the conditions and the time of rendering the health services, as well as the other rights and obligations of the public healthcare institutions concerning the provision of continuous carrying out of a healthcare activity.

**Organization and coordination of the performance of the healthcare activity at primary level by the medical center**

**Article 213**

(1) The medical center, for the purpose of ensuring the functioning and carrying out of the healthcare activity at primary level for the citizens in the area for which it is established in accordance with the primary level network, and on the basis of the agreement concluded with the license holders in the network, shall organize and coordinate the performance of the healthcare activity at primary level,
and it shall particularly organize and schedule the on-duty work, the provision of emergency medical care, provide, that is, organize the performance of the healthcare activity during holidays, holidays and other absences, as well as it shall organize and coordinate other activities.

(2) The medical center shall be obliged to prepare plans for protection in crisis and emergency events and circumstances and, on its own or together with other public and private healthcare institutions from the neighboring territories, to organize health protection and sufficient number of healthcare teams so that they could together ensure continuous 24-hour emergency medical care.

(3) In crisis and emergency events and circumstances, the medical center shall also be obliged to engage other legal entities and natural persons in order to ensure transport for the people who need to be rescued, and other services to respond to the healthcare needs of the population in such circumstances.

(4) The medical center may organize performance of separate activities in organizational units outside its head office so that it may, as much as possible, bring closer to the population in particular the activities of preventive healthcare activity for children and youth, dental health protection for children and polyvalent district nursing activity.

**Regulation of the organization and performance of the healthcare activity**

**Article 214**

The healthcare institutions in the network shall, by their general acts, regulate the organization and the performance of the healthcare activity, that is:

- regarding the emergency medical care activity, 24 hours continuously,
- regarding the primary healthcare activity, by organizing the work in one or two shifts, by adjusting the working hours, and by constant readiness and on-duty work, in accordance with the needs of the population,
- regarding the specialist and consultative healthcare activity, by organizing the work in one or two shifts and by adjusting the working hours, in accordance with the needs of the population, and
- regarding the hospital healthcare activity, by organizing the work in one or more shifts and by providing special working conditions (on-duty work and constant readiness), in accordance with the needs of the population.

**Daily and weekly rest of healthcare workers and co-workers**

**Article 215**

(1) The healthcare worker and the healthcare co-worker shall be entitled to a daily rest in duration of at least 12 uninterrupted hours in the course of 24 hours and to a weekly rest in duration of at least 24 uninterrupted hours plus an additional 12 hours daily rest.

(2) As an exception to paragraph (1) of this Article, and in the cases of significant increase of the work burden, if it is necessary for the continuation of the provision of a health service, if it is necessary for the elimination of the damage of the means of work that would cause suspension of the work, if it is necessary for the assurance of safety of the people and the property, or in other cases determined by law or by a collective agreement, the working hours may last uninterruptedly for 16 hours at the most, provided that the healthcare worker, that is, the healthcare co-worker agrees in writing thereto, and the consent must contain the number of overtime hours the worker agrees to and the time period it refers to.

(3) The employer shall keep records of the working hours, the work carried out beyond the working hours, the healthcare workers and the healthcare co-workers who have given the consent referred to
in paragraph (2) of this Article, and other records of the working hours in accordance with the regulations in the field of labor relations.

(4) The limitations with regard to the work carried out beyond the working hours and the provision of the daily and weekly rest shall also apply to the healthcare workers who, on the basis of a consent from the employer, perform an additional activity in accordance with Article 223 of this Law, in which case the working hours at the employer and the time for performing the work in another healthcare institution are summed up.

(5) In the case of inability to ensure the minimum daily or weekly rest referred to in paragraph (1) of this Article, the employer of the healthcare worker, that is, the healthcare co-worker shall be obliged to ensure rest immediately after the termination of the work referred to in paragraph (2) of this Article.

**On-duty work**

**Article 216**

(1) The healthcare institution may introduce on-duty work to ensure continuous 24-hour healthcare activity, only if the organization of the work in shifts would not ensure continuous performance of the healthcare activity.

(2) The healthcare worker who is on-duty shall be obliged to be present in the healthcare institution during the hours he/she is on-duty.

(3) The on-duty work referred to in paragraph (1) of this Article may be introduced at night time, during holidays determined by law and during days off.

(4) The decision on the introduction and the scope of the on-duty work in the healthcare institution, as well as on the assignment of a healthcare worker who should be on-duty, shall be adopted by the director of the healthcare institution upon consent obtained by the minister of health.

(5) The healthcare worker who is assigned to be on-duty by a decision shall be entitled to a salary compensation for the on-duty work in accordance with the law and the collective agreement.

**Special cases of on-duty work**

**Article 217**

(1) A healthcare worker at the age of 57 for a woman and 59 for a man, a mother of a child younger than the age of three, or a parent who looks after a child with mental and physical impairment shall have the right not to be on-duty.

(2) A healthcare worker who exercises the right referred to in paragraph (1) of this Article shall be obliged to notify the director of the healthcare institution in writing no later than three months as of the day he/she requires to exercise the right.

(3) As an exception to paragraph (1) of this Article, the healthcare worker shall be obliged, at the request of the director of the healthcare institution, to be on-duty in the following cases:
- in the cases of natural or other disasters, epidemics and in other cases where the human life and health are threatened, due to which the load of work in the provision of uninterrupted healthcare activity has increased,
- where the human life and health are threatened and it is otherwise impossible to organize 24-hour performance of the healthcare activity, but only during the time it is necessary to save human lives
and health,
- where, due to the age structure of the healthcare workers, there are no other organizational possibilities for ensuring 24-hour uninterrupted performance of the healthcare activity in the healthcare institution, and
- where the ensuring of 24-hour performance of healthcare activity is threatened due to absence of healthcare workers, but only during the absences.

(4) The healthcare worker shall be on-duty in the cases referred to in paragraph (3) lines 3 and 4 of this Article on the basis of a written request of the director of the healthcare institution.

Readiness

Article 218

(1) The readiness shall be a form of work where the healthcare worker, that is, the healthcare co-worker does not have to be present in the healthcare institution, but shall be obliged to be available on phone or via other telecommunication means in order to provide recorded advising and, if necessary, to come to work in order to provide emergency and urgent medical intervention.

(2) The hours of readiness shall not be regarded as hours within the working hours, except the hours for engaged on call.

(3) The longest acceptable time for arriving at work in cases of engaged on call (readiness) shall be determined by the healthcare institution by a general act.

Salary and part of the salary for job performance

Article 219

(1) The basic salary shall be determined depending on the requirements of the job for which the healthcare worker has concluded an employment contract and the level of complexity established by a collective agreement, and depending on the job performance determined by a collective agreement.

(2) The criteria and measurements for determining the results of the work of the healthcare workers, taking into consideration the scope, the quality of the services, the savings in the work process, and the efficiency in the use of the working hours shall be determined by a collective agreement, an employment contract or an act.

(3) The results of the work of the healthcare worker shall be determined, that is, assessed by the healthcare worker who manages and organizes the work process, that is, by the employer.

(4) If the employer anticipates calculation of the salary in line with paragraphs (1) and (2) of this Article, the healthcare worker shall be guaranteed the payment of salary in accordance with law and collective agreement.

(5) The Ministry of Health may pay a monetary reward to healthcare workers and healthcare co-workers employed in public healthcare institutions who have demonstrated the best results in the work, considering the load, quality of services, savings in the work process, or efficiency in the use of the working hours.

(6) The detailed criteria, the amount and the manner of payment of the monetary reward referred to in paragraph (5) of this Article shall be prescribed by the minister of health.

Supplement for on-duty work and readiness
Article 220

(1) The supplement for on-duty work shall be a composing part of the salary of the healthcare worker and the healthcare co-worker in accordance with the branch collective agreement.

(2) The healthcare worker, that is, the healthcare co-worker shall be entitled to a supplement for the hours of engaged on call during the time of readiness in accordance with the branch collective agreement.

Agreement for uninterrupted performance of the healthcare activity

Article 221

(1) If the uninterrupted performance of the healthcare activity in a public healthcare institution is not possible because of lack of personnel, and upon previously established need and consent from the employee and previous consent from the minister of health, the public healthcare institutions may conclude a mutual agreement on performance of health services, for the purpose of ensuring continuous exercise of health protection.

(2) The agreement referred to in paragraph (1) of this Article shall regulate the rights and obligations of the public healthcare institutions, and in particular the obligation of the public healthcare institution where the healthcare worker performs the activities to pay the institution where the healthcare worker is employed an appropriate compensation for the completed work during the time he/she performed the activities therein, but at least in the amount of the gross salary the employee would earn for that time in the healthcare institution where he/she is employed, the conditions and the time period for performing the healthcare services, as well as the other rights and obligations of the public healthcare institutions concerning the provision of uninterrupted performance of the healthcare activity.

(3) The types of costs that may be included in the compensation referred to in paragraph (2) of this Article shall be prescribed by the minister of health.

Additional activity

Article 222

(1) The healthcare workers – specialists employed in a healthcare institution, who perform specialist-consultative and hospital healthcare activity and who have more than two years of work experience in their specialty, may provide health services as an additional activity eight hours per week at the most, after the regular working hours, in accordance with the license for work of the institution where he/she is employed or in another healthcare institution registered for the same activity.

(2) The healthcare workers referred to in paragraph (1) of this Article shall not have the right to provide health services as an additional activity in the cases of decreased job performance.

(3) The price list and the manner of performing the additional activity shall be prescribed by the minister of health.

(4) The price of the healthcare service provided through the additional activity shall be consisted of two components, that is, compensation for the costs of the healthcare institution and compensation for the team, that is, the healthcare worker.

(5) The compensations referred to in paragraph (4) of this Article shall be paid to a separate (special) account of the healthcare institution for an additional activity.
(6) The healthcare workers referred to in paragraph (1) of this Article shall conclude an agreement on provision of health service as an additional activity in the healthcare institution.

(7) The healthcare workers referred to in paragraph (1) of this Article may provide health services as an additional activity in private healthcare institutions under the conditions laid down by this Law, as well as the price list and the manner of performing an additional activity determined by the bylaw referred to in paragraph (3) of this Article, solely on the basis of an agreement concluded between the public healthcare institution and the private healthcare institution wherein the additional activity is to be performed.

(8) The agreement concluded between the public healthcare institution and the private healthcare institution wherein the additional activity referred to in paragraph (7) of this Article is to be performed shall particularly regulate the payment of the additional activity.

(9) On the basis of the agreement referred to in paragraph (8) of this Article, the healthcare worker referred to in paragraph (7) of this Article shall conclude an agreement with the public healthcare institution in which he/she is employed, which shall regulate the manner of payment of the additional activity referred to in paragraph (7) of this Article.

(10) The public healthcare institution, within a period of three days as of its conclusion, shall submit the agreement concluded between the public healthcare institution and the private healthcare institution wherein the additional activity referred to in paragraph (7) of this Article is to be performed to the Ministry of Health which shall supervise the implementation of the agreement.

(11) The prices prescribed by the bylaw referred to in paragraph (3) of this Article, increased by 20%, shall be valid for the health services provided as an additional activity in the private healthcare institutions.

(12) The director of the public healthcare institution shall, depending on the degree of fulfillment of the conditions for rendering health services as an additional activity of the healthcare workers, designate a healthcare worker of paragraph (1) of this Law who shall provide a health service as an additional activity in the private healthcare institution with which it has concluded an agreement pursuant to paragraph (7) of this Article, based on a previously established list of healthcare workers referred to in paragraph (1) of this Article, who shall, in accordance with the established order on the list, provide a health service as an additional activity.

(13) If the private healthcare institution referred to in paragraph (12) of this Article requires a particular healthcare worker referred to in paragraph (1) of this Article to provide a particular health service as an additional activity, the prices prescribed by the bylaw referred to in paragraph (3) of this Article shall apply, increased by 35%.

(14) The private healthcare institutions shall pay the compensations for the rendered services pursuant to paragraph (7) of this Article to a separate (special) account of the public healthcare institution referred to in paragraph (5) of this Article.

(15) The public healthcare institution shall be obliged to conclude the agreement referred to in paragraph (8) of this Article with all the private healthcare institutions that shall require conclusion of such an agreement under the same conditions.

Requirements for performance of an additional activity

Article 223
(1) The healthcare worker shall perform an additional activity in a public healthcare institution of 30% at the most of the load and the type of each service individually of the total number of provided individual services of that type in the previous month.

(2) A healthcare worker who has been approved the performance of an additional activity may perform 10% of the services established in accordance with paragraph (1) of this Article in a private healthcare institution under the conditions determined in Article 222 paragraph (2) of this Law.

(3) As an exception to paragraph (1) of this Article, in the event of a need for performance of complex medical intervention, the minister of health or a person authorized by him/her may, no more than ten times a year, give consent to a healthcare institution to perform a particular health service as part of the additional activity, two times a year for the healthcare institution at the most.

(4) The health service provided as an additional activity shall be completely covered by the patient as an insured and not insured person. As an insured person, the patient shall have no right to request compensation of the costs for the health service provided as an additional activity from the Fund.

**Written report on performance of an additional activity**

**Article 224**

(1) The healthcare worker who has provided the health service as an additional activity shall be obliged to draw up a written report on performance of an additional activity.

(2) The healthcare worker referred to in paragraph (1) of this Article shall be obliged to make a special procurement of medicaments, medical devices and expendables for the needs of the additional activity.

(3) The healthcare worker referred to in paragraph (1) of this Article shall be obliged to submit a copy of the written report and the collective records of the incurred costs in accordance with the procurements referred to in paragraph (2) of this Article to the public healthcare institution that provides healthcare activity where the additional activity has been performed. Copies of the procurements referred to in paragraph (2) of this Article shall be an integral part of the written report.

(4) The institution referred to in paragraph (3) of this Article shall be obliged to keep the written report and the records of the incurred costs three years as of the day of their submission.

**Obligation to provide continuous medical care during a 24-hour period**

**Article 225**

(1) The healthcare institution, within the scope of its activity, shall be obliged to provide health protection to a patient who requests such protection.

(2) The healthcare institution shall be obliged to ensure conditions for providing continuous medical care during a period of 24 hours, to have medicaments and sanitary materials for providing emergency medical care.

(3) The emergency medical care shall be provided by a balanced distribution of the working hours, by work in shifts, on-duty work, readiness or combination of those forms of work.

(4) The healthcare institution having provided emergency medical care shall be obliged to organize suitable transport and medical care of the patient in need of referral to another healthcare institution until he/she is admitted therein.
(5) Healthcare identification card and referral shall not be required in advance for an emergency medical care.

**Obligation of the hospital healthcare institutions**

**Article 226**

(1) The healthcare institution that performs hospital healthcare activity, within the scope of its activity, shall be obliged to admit the patient to hospital treatment or to ensure admission in another healthcare institution, except if it is not an urgent case or the admission is assessed as unnecessary by the authorized doctor.

(2) The healthcare institution shall be obliged to give the patient a written explanation of the reasons for the rejection of the admission for hospital treatment.

**Video surveillance in the public healthcare institutions**

**Article 226-a**

(1) For the purpose of protecting the human life and health, as well as ensuring control over the entry and exit from the premises of the public healthcare institutions, video surveillance over the premises of the public healthcare institutions shall be conducted by the public healthcare institution, which may be accessed by the Ministry of Health as well.

(2) The area around the counters and the area in front of the premises of the public healthcare institution where health services are provided for the patients, as well as the premises of the healthcare institution where the counter employees work shall be under video surveillance referred to in paragraph (1) of this Article.

(3) A notification shall be displayed in the public healthcare institutions under video surveillance referred to in paragraph (1) of this Article which is unambiguous and visible and displayed in a manner that would enable the persons under video surveillance to be informed about the video surveillance and which contain information that the public healthcare institutions is conducting video surveillance and information on how to get information about where and how long the recordings of the video surveillance system are kept.

(4) The provisions of the Law on Personal Data Protection shall also apply to the video surveillance referred to in paragraph (1) of this Article.

(5) The video surveillance system referred to in paragraph (1) of this Article shall provide detection of a crowd in the premises under video surveillance and a notification of the crowd to the director of the public healthcare institution managed by one director, that is, to the organizational director in the public healthcare institution managed by two directors, as well as to the Ministry of Health.

(6) If there is a crowd as referred to in paragraph (5) of this Article, the Ministry of Health and the director referred to in paragraph (5) of this Article shall receive a notification, whereby the director shall be forthwith obliged to take measures for clearing up the crowd and for ensuring uninterrupted performance of the healthcare activity.

(7) The counters in the public healthcare institutions shall be provided with one-way telephone communication from the director referred to in paragraph (5) of this Article and the Ministry of Health to the counter in order to ensure direct communication for the purpose of clearing up the crowd and ensuring uninterrupted performance of the healthcare activity.
Formation of expert commissions for review of cases of patients with malignant diseases

Article 226-b

(1) For the purpose of providing an adequate treatment to a patient with malignant diseases covering the making of all the appropriate diagnostic tests, reviewing the possible options for further treatment and giving appropriate recommendations for treatment of each patient with malignant diseases, the minister of health shall form expert commissions for review of the cases of patients with malignant diseases (hereinafter: expert commission for malignant diseases).

(2) A multidisciplinary approach in the planning of the treatment of the patient involving doctors of medicine who meet the criteria with regard to the specialization, that is, subspecialization and the experience in the respective field of specialization, that is, subspecialization shall be applied in the work of the expert commissions for malignant diseases.

(3) Separate expert commissions for malignant diseases according to areas shall be formed for the needs of the public healthcare institutions that carry out a healthcare activity at tertiary level (university clinics and university clinical center), that is, at least one commission for each of the following areas particularly: hematology, gastroenterohepatology, urology, breasts, lungs, gynecology, head, neck, soft tissues, musculoskeletal tumors and pediatrics.

(4) One expert commission for malignant diseases shall be formed in each clinical hospital and in each general hospital which shall review the cases of patients with malignant diseases in all areas listed in paragraph (2) of this Article.

(5) The expert commission for malignant diseases referred to in paragraphs (3) and (4) of this Article shall have a term of office of two years and shall be composed of at least six members, out of whom at least one specialist in medical oncology, radiation oncology, surgical oncology, pathology, diagnostic radiology and a doctor of medicine - specialist who is directly involved in the treatment of the patient with malignant disease which is the subject of the review. The members of the commission shall have deputies. The members and the deputies of the expert commission for malignant diseases shall have the right to re-appointment.

(6) The president of the expert commission for malignant diseases shall be selected from among the members.

(7) The expert commission for malignant diseases shall have a coordinator who shall be appointed during the formation of the commission and he/she shall not be a member of the commission.

(8) The members of the commission shall be paid a monthly remuneration for the work in the expert commission for malignant diseases in the amount of 70% of the minimum salary in the Republic of Macedonia in accordance with the regulations determining the minimum salary in the Republic of Macedonia.

(9) If all of the required specialists are not employed in the public healthcare institutions referred to in paragraphs (3) and (4) of this Article, a telemedical meeting of the expert commission for malignant diseases may be held by connecting with other specialists, that is, subspecialists from other healthcare institutions.

Cases that are reviewed at the meetings of the expert commission for review of cases of patients with malignant diseases

Article 226-c
(1) The doctor of medicine who has diagnosed the malignant disease shall be obliged to deliver each new case which is provided outpatient or hospital treatment, together with the recommended plan for further treatment, to the expert commission for malignant diseases and to enter it in the register of malignant diseases.

(2) Other cases of patients with malignant diseases (recurrent or metastatic malignant disease) can be also reviewed at the meetings of the expert commission.

**Manner of work of the expert commission for review of cases of patients with malignant diseases**

**Article 226-d**

(1) The expert commission for malignant diseases shall work at work meetings where the medical conditions and the treatment of the patients with malignant diseases shall be analyzed and discussed.

(2) The meetings of the expert commission for malignant diseases shall be held at least once a week, in duration of at least one hour.

(3) All the members of the expert commission for malignant diseases shall be obliged to participate with their own opinion in the work of the expert commission for malignant diseases.

(4) Records of attendance of the members of the expert commission for malignant diseases and minutes of the work shall be kept for each meeting.

(5) Minutes in a written form and/or in a form of an electronic video or audio-video recording shall be kept for each meeting held, in a form, manner and with contents determined by the minister of health.

(6) All members and deputies of the expert commission for malignant diseases shall be obliged to keep the information presented at the meetings as a business secret.

(7) As an exception, on a request of a members of the expert commission for malignant diseases and upon a prior consent of the president of the expert commission for malignant diseases, and depending on the case which is reviewed at the meeting, that is, the educative purposes, other persons such as: the chosen doctor, a social worker, pharmacist employed in a public healthcare institution at tertiary level having specialization (clinical pharmacology or pharmacoinformatics), specialist in nuclear medicine, specialist in genetics, residents, as well as students of medicine may attend the meetings.

(8) The patients or their authorized representatives (members of the family, relatives, proxies and legal representatives), or representatives from the pharmaceutical industry cannot attend the meetings of the expert commission for the purpose of ensuring confidentiality of the data of the patient and impartial analysis of the cases.

**President of the expert commission for review of cases of patient with malignant diseases**

**Article 226-e**

(1) The work of the expert commission for malignant diseases shall be led by the president of the commission and shall be coordinated by a coordinator of the expert commission.

(2) The president of the expert commission for malignant diseases shall be responsible for the work of the expert commission for malignant diseases, and especially for:
- forwarding the selected cases for presentation before the expert commission for malignant diseases,
- leading the discussions within the framework of the time set,
- participation of all members in the work of the commission, and
- ensuring confidentiality of the data on the patient by all the participants in the work of the commission.

**Coordinator of the expert commission for review of cases of patients with malignant diseases**

**Article 226-f**

The coordinator of the expert commission for malignant diseases shall be responsible for the administrative and technical activities related to the holding of the meetings of the expert commission for malignant diseases, and especially for:
- preparation and organization of the meeting of the expert commission,
- compilation of a list of cases of patients with malignant diseases based on the cases forwarded by the members of the expert commission,
- scheduling meetings and ensuring the necessary equipment,
- delivery of invitations to the members of the expert commission,
- ensuring the complete, updated information about the patients with malignant diseases that are going to be discussed at the meeting, and
- keeping records of how many cases are forwarded and how many are discussed about at the meetings of the expert commission.

**Members of the expert commission for review of cases of patients with malignant diseases**

**Article 226-g**

The members of the expert commission for malignant diseases shall have the obligation, at the meetings, to:
- discuss about the options for treatment of the patients whose cases are reviewed at the meeting and about the conclusions and the final recommendations for treatment,
- forward new cases from their clinical practice, as well as other cases of malignant diseases (for example, recurrent malignant disease) which would benefit from the discussion of the expert commission for malignant diseases,
- before each meeting, forward the new cases of malignant diseases to the coordinator of the expert commission for malignant diseases and to communicate the relevant information about the patient, including the data in the field of radiology and pathology, as well as the specific issues that should be discussed by the multidisciplinary team,
- present the cases of patients to the expert commission for malignant diseases, preserving the confidentiality of the information about the patient,
- give an expert opinion from their own field, and
- enter the recommendations of the expert commission for malignant diseases, the discussion about the recommendations between the doctor and the patient, and the final decisions of the patient related to the treatment in the medical file of the patient.

**Report of the expert commission for review of cases of patients with malignant diseases**

**Article 226-h**

After the discussion about each of the cases separately, the expert commission for malignant diseases shall prepare a report containing the joint findings, conclusions and recommendations for the further treatment, which is signed by all the members of the commission and which represents an integral part of the medical file of the patient.
Manner of organization of the work of public healthcare institutions that carry out a hospital healthcare activity in the field of surgery

Article 226-i

(1) For the purpose of performing an adequate surgical intervention and providing recommendations for the manner of performing the surgical intervention, the professional collegium in the public healthcare institutions at secondary level and tertiary level that carry out a hospital healthcare activity in the field of surgery shall be introduced to the operational plan for all surgical interventions and the plan for particular surgical interventions within one day before the intervention at the latest, after which the professional collegium shall approve the operational plan for all surgical interventions and the plan for particular surgical interventions (hereinafter: procedure for approval of the plans for surgical intervention).

(2) The procedure for approval of the surgical intervention shall be conducted for each patient who is to undergo an elective surgical intervention.

(3) As an exception of paragraph (1) of this Article, the procedure for approval of the plans for surgical intervention shall not be conducted in urgent cases.

(4) After the discussion about each of the case separately, the professional collegium shall prepare a report containing the joint findings, conclusions and recommendations about the course of the surgical intervention, which is signed by all the members of the professional collegium.

(5) The members of the surgical team shall be obliged to inform the professional collegium about the possible changes in the plan for a particular surgical intervention, provided that the intraoperational finding does not correspond to the preoperational diagnostic.

IX. LICENSES FOR CARRYING OUT A HEALTHCARE ACTIVITY IN THE NETWORK OF HEALTHCARE INSTITUTIONS

Determination of the license and the license holders

Article 227

(1) The healthcare institutions that meet the requirements determined by this Law may carry out a healthcare activity at primary, secondary and tertiary level in the network only on the basis of a license for carrying out a healthcare activity in the network of healthcare institutions.

(2) Healthcare activity of a family, that is, general medicine, school medicine, labor medicine if performing the work as a family, that is, a general practitioner, pediatrics, gynecology and obstetrics, dental health protection, and pharmaceutical activity may be performed in the network at primary level, on the basis of a license.

(3) The license for carrying out the healthcare activity referred to in paragraph (1) of this Article shall be granted for a period of up to 35 years to a healthcare institution or to a natural person – healthcare worker with a corresponding license for work.

(4) If the license for carrying out the healthcare activity is granted to a natural person as referred to in paragraph (3) of this Article, the person shall be obliged to establish a private healthcare institution in the time period determined by the decision on granting the license.
(5) If the natural person referred to in paragraph (3) of this Article does not establish a private healthcare institution in the time period determined by the decision on granting the license or does not file an application for issuance of a license for work within a period of seven days as of the day of establishment of the institution, the granted license shall be revoked.

Applicable regulations and documentation for the license granting announcement

Article 228

(1) The regulations on concessions and other types of public private partnership shall not apply to the granting of the license, unless otherwise regulated by this Law.

(2) An integral part of the documentation for the license granting announcement shall be:
- for a healthcare institution – a license for work and a work agreement or a statement for work of the persons in the team, verified by a notary and
- for a natural person – a license for work, a proof of available premises and equipment for performing the appropriate activity which is subject of granting the license and an agreement for work or a statement for work of the persons in the team, verified by a notary.

Granting of a license

Article 229

(1) The license granting procedure shall be conducted by the Ministry of Health.

(2) The license granting procedure for each new separate license shall commence at least three months before the expiry of the period for which the existing license has been granted.

(3) In order to commence the license granting procedure, the Ministry of Health shall adopt a decision on commencement of the license granting procedure.

(4) The decision on commencement of the license granting procedure referred to in paragraph (3) of this Article shall particularly contain:
- an explanation of the justification to grant a license,
- a statement of its aims,
- a subject-matter of the license and basic requirements for license granting,
- a type of license granting procedure,
- a calculation of the amount and the manner of payment of the license fee,
- a manner and deadline for conducting the license granting procedure, and
- an amount of the fee for issuing the tender documentation.

(5) An "open call" shall be a license granting procedure where every interested person who has taken the tender documentation may make bids for concluding a license agreement.

(6) The minimum number of eligible bidders should be at least one.

(7) The license granting procedure shall be prepared, organized and implemented by the commission for implementation of license granting procedure (hereinafter: the commission) formed by the minister of health.

(8) The commission referred to in paragraph (1) of this Article shall be composed of a president, deputy president and at least three members and their deputies.
(9) Persons from among the employees in the Ministry of Health and experts in the appropriate field for which the license is being granted shall be appointed as members of the commission.

(10) Members of the commission cannot be persons who:
- are married, related up to the second degree or related by adoption or guardianship to the bidder or the candidate, his/her legal representative, and in the cases where the bidder or the candidate is a legal entity, to the members of its governing, supervisory or other bodies and management bodies as well,
- during the last three years, have been employed or have been members of the governing bodies of the candidate, or
- are in other legal or factual relationship with the candidate.

(11) The commission shall work in plenary sessions and shall adopt the decisions by the majority of votes of the members.

(12) The commission shall:
- prepare the tender documentation,
- announce the public call,
- organize the acceptance of applications and bids,
- give explanations and submit additional information and documents,
- review and assess the bids and rank the candidates proposing the first-ranked to be selected as a license holder,
- submit a proposal for termination of the procedure, and
- perform other activities necessary for implementation of the procedure.

(13) The commission shall notify all the bidders and candidates about the activities taken in the procedure.

(14) The commission shall be obliged to prepare the tender documentation within the period determined by the decision on commencement of the license granting procedure, upon a previously obtained consent from the minister of health.

(15) The commission may entrust the preparation of the tender documentation to a scientific or professional organization or to experts in the appropriate field.

(16) Depending on the nature of the license, the tender documentation shall particularly contain the following elements:
- an invitation to submit a bid, including instructions,
- requirements it must meet, including also the technical specifications,
- criteria for assessment of the bids,
- instructions for the bidders how to prepare the bid,
- a period for which the license is granted,
- a draft text of the license agreement, and
- other requirements depending on the subject-matter of the license.

(17) A copy of the decision on commencement of the license granting procedure, as well as a draft of the license agreement, shall be attached to the tender documentation for participation in the procedure.

(18) The license agreement shall regulate the mutual rights and obligations under the granted license between the Ministry of Health and the license holder.

(19) The license agreement concluded with the healthcare institution being granted the license shall mandatorily contain provisions on:
- the type of healthcare activity to be performed on the basis of the license,
- the commencement of the license use,
- the license granting for a period of up to 35 years, 
- the license fee, 
- the premises and equipment for performance of the healthcare activity, 
- the data on the people with whom the license holder shall work in a team, and 
- provisions on the obligation of the license holder to require previous consent from the Ministry of Health for each change pertaining to the contents of the license agreement, and especially change of the person who is on the team of the license holder and change of the premises where the license holder performs the activity.

(20) The license agreement concluded with the healthcare institution being granted a license shall mandatorily contain the provisions referred to in paragraph (19) lines 1, 2, 3, 4, 5 and 7 of this Article.

(21) Abolished 35

(22) The minister of health shall approve the tender documentation.

**License granting procedure**

**Article 230**

(1) The commission shall be obliged to make possible for the interested candidates to take tender documentation immediately after the date of announcement of the public call.

(2) The Ministry of Health may charge the bidders and the candidates a fee for issuing the tender documentation.

(3) The amount of the fee referred to in paragraph (2) of this Article shall be calculated on the basis of the actual costs incurred for the activities necessary for its preparation.

(4) The Ministry of Health may amend the tender documentation, provided that it is available to the interested candidates six days prior to the expiry of the deadline for submission of bids or applications for participation at the latest.

(5) Upon approval of the tender documentation, the commission shall announce the public call for submission of bids for license granting in the “Official Gazette of the Republic of Macedonia”.

(6) The public call referred to in paragraph (5) of this Article shall particularly contain:
- an explanation of the justification for granting a license,
- a statement of its aims,
- a subject-matter of the license and basic requirements for license granting,
- a type of license granting procedure,
- a calculation of the amount and the manner of payment of the license fee,
- a manner and deadline for implementation of the license granting procedure, and
- an amount of the fee for issuing the tender documentation.

(7) The deadlines for submission of bids and the application for participation shall be accordingly published and determined depending on the complexity of the license granting procedure and the time reasonably required to prepare the bid, but they shall not be shorter than the deadlines determined by this Law.

(8) The deadlines may be extended by the Ministry of Health at any time prior to the expiry of the deadline itself, provided that the bidders and the candidates are informed timely thereof.
(9) The deadlines shall be extended if the tender documentation has not been submitted on time to all
the bidders or candidates, if there has been an amendment to the public call and/or the tender
documentation, as well as in other cases where the Ministry of Health establishes justification for
extension of the deadlines for objective reasons.

(10) The deadlines shall start running as of the day the call is sent for announcement.

(11) Unless otherwise regulated by this Law, the submission of bids and applications for participation:
a) in the case of an open call, cannot be shorter than 26 days as of the day of sending the call for
announcement.

(12) The bid and the application for participation shall be submitted in a manner and form determined
by the public call.

(13) The persons who have taken the tender documentation shall have the right to submit bids and an
application for participation.

(14) The bidder, that is, the candidate may submit only one bid, that is, one application for
participation.

(15) The participation in the procedure for submission of bids may be conditioned by providing a
guarantee by the bidder in a form of deposited funds or a bank guarantee that cannot be lower than
3% of the assessed value of the license.

(16) If the bidder provides the guarantee in the form of deposited funds, they shall be paid to an
appropriate account within the treasury account.

(17) The Ministry of Health shall be obliged to return the deposited amount, that is, the guarantee to
all the bidders which have participated in the license granting procedure, except to the first- and the
second-ranked bidder, no later than seven days as of the day of adoption of the decision on selection
of a license holder, that is, the most favorable bidder. The Ministry of Health shall be obliged to return
the deposited amount, that is, the guarantee to the first- and the second-ranked bidder within a
period of 14 days as of the day of conclusion of the license agreement.

(18) The guarantee referred to in paragraph (17) of this Law shall be called for the benefit of the
Ministry of Health if:
- the bidder withdraws the bid after the deadline for submission of bids,
- the first-, that is, the second-ranked bidder refuses to conclude the license agreement, and
- the most favorable bidder does not meet particular requirements for return of the guarantee for
participation in the procedure, anticipated by the tender documentation.

(19) After the expiry of the deadline for submission of bids, the commission shall publicly open the
bids in the presence of authorized representatives of the bidders in a place and at a time determined
by the public call.

(20) The public opening of the bids shall be conducted in a manner determined by the public call.

(21) The commission shall prepare minutes of the public opening of the bids.

(22) The commission shall establish a list of candidates on the basis of their personal standing, their
ability to perform professional activity, their economic and financial situation, as well as their technical
and professional ability.

(23) The commission shall evaluate the bids only of those bidders selected as favorable.
(24) The commission shall publish a report on the completed evaluation and shall notify all the bidders about the results of the selection procedure.

(25) **Abolished**

(26) The Ministry of Health shall also mandatorily exclude the candidate or the bidder where:
- there is an open bankruptcy or liquidation procedure,
- it has been imposed a sentence for a crime or a misdemeanor sanction prohibition to perform an activity,
- there is no complete tender documentation submitted.

(27) The Ministry of Health may require the bidders and the candidates to prove their membership or inclusion in a professional association or organization entered in an appropriate register or to submit a special statement or reference in order to prove their right and ability for performance of a professional activity.

(28) The minister of health may require the bidders or the candidates to prove their technical and professional ability to execute the subject-matter of the license.

(29) Criterion on the basis of which the Ministry of Health shall base the selection of the best bid shall be the financially most favorable bid or economically most favorable bid.

(30) Economically most favorable bid shall be evaluated on the basis of the criteria related to the performance and functional requirements that include quality, price of works and services, current costs, economic profitability compared to the costs.

(31) The methodology for expressing the criteria in points shall be adopted by the minister of health.

(32) The commission shall prepare a written report on the evaluation for each license granting procedure.

(33) The report on the evaluation and the proposal of the decision on selection of the most favorable bid shall be signed by the president and the members of the commission and it shall be submitted to the minister of health.

**License granting**

**Article 231**


(2) In the process of awarding the next license after the expiry of the validity period of the license granted, priority for selection of the most favorable bid over the other criteria shall be the current status of the license holder in accordance with this Law.

(3) The commission for implementation of the license granting procedure, after conducting the procedure, shall submit a proposal to the minister of health for:
- selection of the most favorable bid together with a ranking list of candidates and
- termination of the procedure.
(4) The minister of health, on the basis of the proposal referred to in paragraph (3) of this Article and the report on the evaluation, shall adopt a decision on:
- selection of the first-ranked candidate as the most favorable bidder or
- imposition of obligation of the commission to eliminate the established irregularities in the license granting procedure and to make a new ranking of the bids or
- termination of the procedure in the cases determined by this Law.

(5) The decision on selection of the most favorable bid shall be final and an administrative dispute may be initiated against it.

(6) The decision referred to in paragraph (5) of this Article shall be submitted to all bidders or candidates within a period not longer than 15 days as of the day of its adoption.

(7) The decision on selection of the most favorable bidder shall be published in the “Official Gazette of the Republic of Macedonia”.

(8) The lowest amount of the license fee, depending on the geographic area where the health activity is to be performed, shall be prescribed by the minister of health.

(9) The license fee shall be revenue of the Budget of the Republic of Macedonia – Ministry of Health and shall be paid to an appropriate account of the Ministry of Health, within the treasury account.

(10) In the process of granting the license to the healthcare institutions where the chosen doctors work, the license granting procedure shall not be implemented, that is, the Ministry of Health on the basis of an application for license granting shall conclude a license agreement, provided that the maximum number of teams for the corresponding healthcare activity and area is not reached in the network of healthcare institutions.

(11) If premises or equipment of a public healthcare institution, which are required for performing the corresponding activity of the license holder, are used in the course of granting a license, the procedure for leasing the premises or the equipment shall be conducted by the public healthcare institution, on the basis of a decision of the governing board of the public healthcare institution and a written consent from the Ministry of Health.

(12) The premises or the equipment shall be leased to the healthcare institution, that is, to the healthcare worker that offers the highest monthly rent on the public bidding.

(13) The lowest amount of rent, depending on the size of the premises, the location of the facility, that is, the position of the premises, the age of the facility and the equipment of the facility shall be prescribed by the minister of health and that amount shall be considered to be the starting amount at the public bidding.

(14) The funds from the rent shall be paid to a separate account of the public healthcare institution and shall be earmarked for ongoing and investment maintenance of the public healthcare institution.

(15) A copy of the agreement on lease of the premises or the equipment concluded between the public healthcare institution and the healthcare institution, that is, a healthcare worker lessee, shall be submitted to the Ministry of Health by the public healthcare institution.

(16) The provisions of the Law on the Usage and Management of Assets of State Bodies pertaining to lease of immovable and movable assets by public bidding shall accordingly apply to the procedure for leasing the premises or the equipment referred to in paragraph (11) of this Article, unless otherwise determined by this Law.

**Termination of the license**
(1) The license shall terminate upon:
- expiry of the validity period of the license agreement,
- unilateral cancellation of the license agreement by the Ministry of Health,
- unilateral cancellation of the license agreement by the license holder,
- agreed cancellation of the agreement,
- bankruptcy or liquidation of the license holder, and
- other cases envisaged by law and the license agreement.

(2) If it is established that the license holder does not perform the activity in accordance with the law, the decision on license granting, that is, the license agreement, the Ministry of Health shall set a time period for elimination of the irregularities.

(3) The license holder shall have the license revoked should it fail to eliminate the irregularities within the time period set by the Ministry of Health by cancelling the license agreement.

(4) In the case of revocation of the license, the Ministry of Health shall ensure the patients to be admitted in a healthcare institution performing a healthcare activity in the network, of patient’s choice.

(5) Upon expiry of the validity period of the license established in the license agreement, provided that the license is not extended in accordance with this Law, the license shall cease to be valid.

(6) In the case of significant violation of the obligations of the license holder envisaged in the license agreement, the Ministry of Health may unilaterally cancel the license agreement in accordance with the provisions of this Article.

(7) The unilateral cancellation of the license referred to in paragraph (1) of this Article may be pronounced when:
- the activity transferred by the license is performed in an inappropriate or low quality manner, considering the rules, parameters and other conditions whereby appropriate performance of the activity established by the license agreement is determined,
- the license holder has significantly violated the provisions of the license agreement or the laws and regulations applicable to the license agreement in another manner,
- the license holder has terminated or caused termination of the provision of the public service,
- the license holder has lost the economic, technical or operative abilities required for performance of the activity under a special law and the license agreement, and
- the license holder has not acted upon the imposed measures in the supervision and control procedure conducted in accordance with a special law.

(8) The pronouncement of the unilateral cancellation shall be done by a decision of the Ministry of Health where the reasons for cancellation of the license and the rights of the license holder upon the adopted decision are state.

(9) Before the adoption of the decision referred to in paragraph (8) of this Article and if the license holder has not acted upon the notification referred to in paragraph (2) of this Article, the Ministry of Health shall be obliged to explain the reasons for the unilateral cancellation to the license holder.

(10) The Ministry of Health shall be obliged, within an optimal time period prior to the adoption of the decision on cancellation of the license, to notify in writing the license holder about the violations referred to in paragraph (7) of this Article and to invite the license holder to correct the flaws in the conduct in order to ensure observance of the agreement within the time period determined by the notification. The time period must be sufficient in order to make possible for the license holder to act upon the notification.
(11) In the case of a significant violation of the obligations by the Ministry of Health envisaged by the license agreement, the license holder may unilaterally cancel the license agreement in accordance with the provisions of this Article.

(12) The license holder shall be obliged, within an optimal period of time envisaged by the license agreement, before pronouncement of the unilateral cancellation of the license, to notify in writing the Ministry of Health about the violations referred to in paragraph (7) of this Article and to invite it to correct the flaws in order to ensure observance of the agreement, within the time period determined in the notification. The time period must be sufficient in order to make possible for the Ministry of Health to act upon the notification.

(13) Upon expiry of the time period referred to in paragraph (2) of this Article, if the Ministry of Health has failed to eliminate the established flaws, the agreement shall be considered cancelled.

(14) The Ministry of Health and the license holder may agreeably cancel the license agreement due to violation of the contractual obligations by the Ministry of Health, that is, by the license holder, in line with the applicable regulations and in line with the provisions of the agreement.

(15) After the termination of the validity period of the license, the license holder shall be obliged to hand over the goods of general interest, all the items, facilities, plants, installations and other assets given thereto on the basis of the license to the Ministry of Health.

(16) The handing over of the goods of general interest, items, facilities, plants, installations and other assets by the Ministry of Health shall be conducted by the commission.

(17) Minutes shall be composed of the handing over of the goods of general interest, all items, facilities, plants, installations and other assets which shall be signed by the president and the members of the commission and by an authorized representative of the license holder.

(18) The handing over of the goods of general interest, all items, facilities, plants, installations and other assets shall be completed within a period of 30 days as of the day of termination of the license.

(19) Where the license holder refuses to hand over the subject of the license after the expiry of the time period referred to in paragraph (18) of this Article, the commission shall compose separate minutes to establish the situation and to inform the Ministry of Health which shall, based on that, adopt a decision on take-over of the subject of the license.

X. QUALITY OF HEALTH PROTECTION AND ACCREDITATION

1. Monitoring and promotion of quality of health protection

Determination of the monitoring and the promotion of quality

Article 233

The monitoring and the promotion of the quality of health protection in the performance of the healthcare activity shall, in terms of this Law, include a procedure for monitoring the quality of the professional work of the healthcare and other institutions performing healthcare activity, the healthcare workers and the healthcare co-workers, as well as a proposal of measures for its promotion.

Manner of carrying out

Article 234
(1) The monitoring and the promotion of the quality of health protection in the performance of the healthcare activity shall be carried out by internal quality monitoring done through the quality indicators, and the promotion of the quality of the health protection in the performance of the healthcare activity shall be done through established accreditation standards.

(2) The types of quality indicators referred to in paragraph (1) of this Article shall be prescribed by the Ministry of Health.

2. Internal monitoring and promotion of quality of health protection

Manner of internal monitoring and promotion of quality

Article 235

(1) The internal monitoring and promotion of the quality of health protection in the performance of the healthcare activity shall be implemented in each healthcare and other institution performing a healthcare activity and over the work of the healthcare workers and co-workers on the basis of an annual program for monitoring and promotion of the quality of healthcare institution.

(2) The healthcare institution performing hospital healthcare activity shall be obliged to form a commission for monitoring and promotion of the quality of health protection (hereinafter: the commission for quality).

(3) The institution referred to in paragraph (1) of this Article shall be obliged to submit the annual program to the Ministry of Health by 31 December in the current year for the following year at the latest.

(4) All healthcare workers and healthcare co-workers shall be obliged to actively participate in the implementation of the annual program for monitoring and promotion of the quality of health protection.

(5) The internal monitoring and promotion of the quality of health protection in the performance of the healthcare activity referred to in paragraph (1) of this Article shall also mandatorily include evaluation of at least 10% of the health services provided by a healthcare worker with a university degree, by another healthcare worker with a university degree, with at least the same educational qualifications as those of the healthcare worker who is being checked, employed at the same healthcare institution, provided that there are more than one healthcare workers with a university degree in the healthcare institution.

Commission for quality

Article 236

(1) The commission for quality shall be composed of at least five members, four of whom shall be healthcare workers, and at least one healthcare worker with a high school, two-year post secondary school or higher vocational degree, as well as one representative of the patients’ associations.

(2) The commission referred to in paragraph (1) of this Article shall, from among its members, elect a coordinator for monitoring and promotion of the quality of health protection within the healthcare institution.

(3) The type of healthcare workers who are members of the commission referred to in paragraph (1) of this Article, depending on the type of activity performed by the healthcare institution, shall be regulated by the statute of the institution.
Scope of operation of the commission for quality

Article 237

The commission for quality shall particularly perform the following activities:
- collect, process and keep the data related to the quality indicators,
- participate in the external quality monitoring,
- implement activities related to the preparation of the accreditation procedure, and
- cooperate with the Agency for Quality and Accreditation of Healthcare Institutions in the implementation of the program for monitoring and promotion of the quality of healthcare activity.

Obligation of the healthcare institutions to deliver reports

Article 238

The healthcare and the other institutions performing healthcare activity shall be obliged to deliver the annual reports on implementation of the activities defined by the program for monitoring and promotion of the quality of health protection to the Agency for Quality and Accreditation of Healthcare Institutions.

Responsibility for the quality of the healthcare activity

Article 239

(1) The healthcare workers and the healthcare co-workers shall be accountable for the quality of the health protection before the head of the organizational unit in the institution, that is, the responsible holder of the healthcare activity.

(2) The head, that is, the responsible holder referred to in paragraph (1) of this Article shall be accountable before the director of the institution regarding the quality of his/her work, as well as regarding the quality of the health protection provided in the organizational unit he/she heads.

3. Accreditation

Definition of accreditation

Article 240

Accreditation, in terms of this Law, shall be a procedure for assessment of the quality of the work of the healthcare institutions, on the basis of application of optimal level of established standards of the work of the healthcare institution in a particular field of healthcare activity, that is, branch of medicine, dental medicine, that is, pharmacy.

Agency for Quality and Accreditation of Healthcare Institutions

Article 241

(1) Agency for Quality and Accreditation of Healthcare Institutions (hereinafter: the Agency), shall be established as an independent state administrative body for performance of administrative, expert and development activities for accreditation of the work of the healthcare institutions.

(2) The Agency shall have the capacity of a legal entity.
(3) The Agency shall be managed by a director, appointed and dismissed by the Government.

(4) Director of the Agency may be appointed a person who, in addition to the general requirements, also meets the following special requirements:
- to have a degree from the faculty of medicine, dental medicine or pharmacy,
- to have at least five years of work experience in the field of health protection, and
- to possess active knowledge of at least one of the world languages.

(5) The Government shall dismiss the director of the Agency:
- upon his/her personal request,
- if there is any of the reasons, due to which, under the labor relations regulations, his/her employment terminates by the force of law,
- if he/she does not act in accordance with the law and the general acts of the Agency,
- if he/she causes damage to the Agency due to negligent and incorrect work,
- if he/she neglects or does not meet the obligations and therefore more serious disturbances occur or might occur in the performance of the Agency's activity, and
- abolished 38

(6) The funds for the work of the Agency shall be provided from the Budget of the Republic of Macedonia, from its own revenues, and from other sources in accordance with this Law or another law.

Competence of the Agency

Article 242

(1) The Agency shall carry out the following activities:
1) develop an accreditation system harmonized with the European and the international practice in this field;
2) deliver education in the field of quality of health protection and accreditation;
3) establish standards for accreditation of healthcare institutions;
4) assess the quality of the provided health protection to patients;
5) grant accreditation to healthcare institutions;
6) rank the healthcare institutions;
7) issue an accreditation certificate (hereinafter: the certificate) and keep records of the issued certificates;
8) perform other activities in the field of quality of health protection and accreditation, in accordance with this Law and the regulations adopted on the basis of this Law.

(2) With regard to the activities referred to in paragraph (1) points 3 and 5 of this Article, the Agency shall decide in an administrative procedure in line with the regulations in the field of the general administrative procedure.

(3) The standards for accreditation referred to in paragraph (1) of this Article shall be determined by the Agency by an act, approved by the Government.

(4) The Agency shall be obliged to submit an annual report for its work to the Government, by 31 March in the current year for the preceding year at the latest.

Accreditation procedure

Article 243

(1) The accreditation shall be mandatory and shall be done upon a request of the healthcare institution.
(2) The healthcare institution shall submit the request for obtaining accreditation to the Agency.

(3) A healthcare institution shall obtain accreditation if the Agency establishes fulfillment of the established standards for a particular field of healthcare activity.

(4) The Agency shall by a decision establish the fulfillment of the standards for accreditation of the healthcare institution, which shall be final in an administrative procedure and an administrative dispute can be initiated against it.

(5) Upon the adoption of the decision referred to in paragraph (4) of this Article, the Agency shall issue a certificate for accreditation to the healthcare institution.

(6) The costs for the accreditation shall be covered by the healthcare institution that has filed the request for accreditation.

(7) The amount of the costs referred to in paragraph (6) of this Article, based on the actual material costs related to the accreditation procedure and the fees for the work of the external evaluators, shall be determined by an act of the Agency, approved by the Government.

(8) The manner of accrediting and assessing the fulfillment of the accreditation standards, as well as the documentation necessary for obtaining accreditation, shall be prescribed by the minister of health upon a proposal of the Agency.

Contents of the accreditation certificate and validity period

Article 244

(1) The certificate referred to in Article 243 paragraph (4) of this Article may be issued for:
- a particular field of healthcare activity performed in the healthcare institutions or
- the overall activity of the healthcare institution.

(2) The certificate shall be issued for a particular period, but five years at the longest.

(3) After the expiry of the period referred to in paragraph (2) of this Article, the accreditation procedure may be repeated on request of the healthcare institution.

(4) The accreditation certificate of the healthcare institution shall be published on the website of the Agency and of the Ministry of Health.

(5) The healthcare institution that has obtained accreditation shall be obliged to report every change concerning the accreditation to the Agency.

(6) The accreditation certificate obtained in accordance with this Law or the certificate recognized by the European Agency responsible for accreditation of the healthcare institutions shall confirm that the healthcare institution meets the nationally, that is, internationally recognized standards for performance of a healthcare activity.

Evaluation of the quality of the work of healthcare institutions, healthcare workers and healthcare co-workers

Article 245
The Agency shall evaluate the quality of the work of the healthcare institutions, the healthcare workers and the healthcare co-workers on the basis of the following criteria:
- its own analysis and findings prepared in line with previously established and internationally accepted indicators,
- data obtained from the completed supervision by the State Sanitary and Health Inspectorate, as well as by the Ministry of Health,
- data obtained from the completed self-evaluation of the quality of the work of the healthcare institutions, the healthcare workers, and the healthcare co-workers, and
- data obtained from the evaluation of the quality of the work of the healthcare institutions, the healthcare workers and the healthcare co-workers made by the patients.

The indicators referred to in paragraph (1) line 1 of this Article shall be determined by the Agency by an act, upon a previously obtained positive opinion from the minister of health.

The Agency shall define, by an act, the criteria for self-evaluation of the quality of the work of the healthcare institutions, the healthcare workers and the healthcare co-workers, as well as the criteria, the manner and the form for evaluation referred to in paragraph (1) line 4 of this Article.

The evaluation referred to in paragraph (1) of this Article shall be carried out by the Agency once a year, in line with the program referred to in Article 241 paragraph (5) of this Law.

The Agency shall, by an act, prepare a scale for evaluation of the data referred to in paragraph (1) lines 1, 2, 3 and 4 of this Article, upon a previously obtained consent from the minister of health.

The Agency shall also, by an act, prepare a scale for evaluation of the overall data referred to in paragraph (1) of this Article, upon a previously obtained consent from the minister of health. In the act, the Agency shall determine the form, the contents and the manner of publishing the annual report on evaluation of the quality of the work of the healthcare institutions, the healthcare workers and the healthcare co-workers.

If the data referred to in paragraph (6) of this Article are negative for the healthcare institution for two years continuously, the Agency may initiate a procedure for revocation of the accreditation of the healthcare institution and/or for dismissal of the director of the healthcare institution.

Depending on the results obtained from the application of the scale for evaluation of the quality of the work of the healthcare workers, that is, co-workers referred to in paragraph (6) of this Article, the Agency may suggest the director of the healthcare institution to increase, that is, to decrease the salary of the healthcare worker, that is, co-worker, in accordance with this Law and a collective agreement.

3-a External control of the quality of laboratory services

Ensuring accuracy and reliability of the results of the conducted laboratory tests

Article 245-a

For the purpose of ensuring accuracy and reliability of the results of the laboratory tests, an external control of the quality of the laboratory services in the healthcare institutions that carry out medical laboratory diagnostic activity (hereinafter: laboratories) shall be made.

The external control of the quality of the laboratory services shall cover biochemical, microbiological, histopathological, cytological, immunological, hematological, genetic tests and tests in the field of molecular medicine.
Regular and extraordinary external control of the quality of laboratory services  

Article 245-b

(1) The external control of the quality of the laboratory services shall be made as a regular and extraordinary control.

(2) The regular external control of the quality of the laboratory services shall be made mandatorily two times a year in precisely determined time period according to an annual plan for conducting quality controls which is adopted by the Ministry of Health until 31 December in the current year for the following year at the latest.

(3) The extraordinary external control shall be conducted upon need, but two times a year at the most.

(4) The costs for conducting the regular and the extraordinary external control of the quality of the laboratory services referred to in paragraph (1) of this Article shall be born by the laboratory where the control is made.

Control samples  

Article 245-c

(1) The control of the quality of laboratory services and the assessment of the accuracy of the used methods shall be made by using control samples with predetermined values set out by the producer, and with unknown concentration and/or content for the laboratory (hereinafter: control sample values) for a large number of biochemical, hematological, immunological and microbiological parameters according to methods standardized under the International Federation for Clinical Chemistry and under the International Standards for External Control of Medical Diagnostic Analyses for Bacteriological, Virusological, Mycological, Parasitological and Serological Diagnostics (hereinafter: control samples).

(2) The results of the measurement shall consist of quantitative (numerical) or qualitative values and measuring units.

(3) The Ministry of Health shall be obliged to procure the control samples for the needs of all laboratories in the Republic of Macedonia for the purpose of making a regular and extraordinary control and to distribute them to the laboratories according to the annual plan referred to in Article 245-b paragraph (2) of this Law.

(4) The analysis of the results of the control shall be made by the producer of the control samples which has been awarded the contract for public procurement of control samples and which shall make the analysis with a special computer program (software).

Acceptable result of the external control of the quality of laboratory services  

Article 245-d

(1) If the values of the tested parameters are around the mean value plus/minus two standard deviations, according to the method standardized under the International Federation for Clinical Chemistry and the used apparatuses, the result of the external control of the quality of laboratory services in healthcare institutions carrying out a biochemical activity shall be deemed acceptable.
(2) The result of the external control of the quality of laboratory services in healthcare institutions carrying out a microbiological laboratory activity which precisely identifies the microorganism according to class, that is, species or subspecies or type or its other characteristics in accordance with the aim of the control sample shall be deemed acceptable.

(3) During the external control of the quality of the laboratory services in healthcare institutions carrying out immunological, genetic tests and tests in the field of molecular medicine, the given opinion of the certified organization which conducts the external control, whether as precise numerical value, percentage or descriptive result, shall be deemed acceptable.

**Determination of the type and number of control samples that are to be procured**

**Article 245-e**

(1) The number and the type of control samples that are to be procured by the Ministry of Health and delivered to the laboratories shall depend on the number of applied laboratories and on the type of tests that the laboratory makes, as well as on the number of regular and extraordinary external controls that are to be made during one year.

(2) The laboratories where control is to be made shall be obliged to apply to the Ministry of Health by submitting a list of all the tests for which each respective laboratory is registered to make until 1 October in the current year at the latest for the purpose of making an external control in the following year.

(3) The Ministry of Health, based on the obtained information from all the laboratories where control is to be made, as well as based on the number of regular and extraordinary external controls that are to be made during one year, shall determine the quantity and the type of the necessary control samples for which it shall make procurement.

(4) The Ministry of Health shall submit the list of applied laboratories to the producer of control samples which has been awarded the public procurement contract, which shall assign identification numbers to the laboratories and shall submit them together with the control sample to the Ministry of Health.

**Values of a control sample**

**Article 245-f**

(1) The control samples shall be procured and shall be marked with a code and shall be delivered to the Ministry of Health without the values of the control sample. These values should not be known to the Ministry of Health, not to the laboratory where external control is made.

(2) The value of the control sample shall be deemed a business secret until the moment of its announcement in accordance with Article 245-h paragraph (4) of this Law and until that moment the producer of the control sample must not make the value of the control sample available to the laboratory.

(3) The selection of the control sample depends on the type of the measuring procedure and the measuring instruments which are at disposal of the laboratory, that is, the methods and the procedure for detection of microorganisms.

(4) Every laboratory, before taking the control samples, should compensate the cost for procurement of the control samples incurred by the Ministry of Health.
Delivery of control samples

Article 245-g

(1) The external control shall cover control over the analytical deviation (inaccuracy) and the analytical variation (imprecision), as well as the accuracy in microorganism identification and its characteristics.

(2) The laboratory shall treat the control samples in conditions that are identical to the everyday conditions and in the same manner as the samples taken from a patient.

(3) The control samples shall be delivered by the producer of control samples which has been awarded the public procurement contract intended for laboratories together with forms for reporting about the received results and instructions for conducting the required procedures.

(4) The identification number of the laboratory referred to in Article 245-e paragraph (3) of this Law, used for reporting of the results, shall be included in the forms for reporting of the received results referred to in paragraph (3) of this Article.

(5) The Ministry of Health and the producer of control samples which has been awarded the public procurement contract shall have the data on the identification number of the laboratory and the code for the control sample submitted to the laboratory, which shall be deemed a business secret.

Processing of control samples and announcement of results

Article 245-h

(1) The laboratories shall be obliged, before the beginning of the period for making the regular external control, to take the control samples from the Ministry of Health and the laboratories that make biochemical, histopathological, cytological, hematological, within a period of 15 days, that is, the microbiological laboratories, within a period of three weeks, that is, the laboratories that make immunological, genetic tests and tests in the field of molecular medicine, within a period of four weeks as of the beginning of the period for regular control determined by the annual plan, to make the testing of the control sample and to enter electronically the result of the testing at the webpage designed and posted for this purpose by the producer of the control sample, to which the laboratories access by an identification number.

(2) The Internet page shall contain a joint reports for all the laboratories in which the values of the control sample marked with a code and the results of each particular laboratory under the identification number of the laboratory shall be entered in particular.

(3) Access to the Internet page shall have the producer of the control sample which has been awarded the public procurement contract, the laboratories where the control is made, and the Ministry of Health.

(4) Upon entry of the received results at the Internet page by the laboratories, the producer of the control sample shall be obliged, at the same Internet page, to enter the values of the control sample for each particular laboratory within a period of 15 days as of the day of entry of the results by the laboratory.

(5) Upon completion of the control, the producer of the control sample shall be obliged to prepare a report of the control in a written form and to submit it to the laboratory that has participated in the control and to the Ministry of Health. The data on the name under which the laboratories are registered, the identification number of the laboratory, the code of the control sample, the result of the control sample, and the results of the external control shall be in particular entered in the report.
(6) The results of the external control shall be used in the procedure for accreditation of the laboratories and shall be kept five years.

**Actions in case of deviation of the control sample values**

**Article 245-i**

(1) If the producer of the control sample, after the processing of the data, establishes that the result received from the laboratory during processing of the control sample deviates from the control sample values, it shall inform the Ministry of Health within a period of three days as of the establishment of the deviation and shall submit a report containing an analysis of the problem and a recommendation for taking a corrective measure for elimination of the mistakes to the Ministry of Health and the laboratory.

(2) The laboratory shall be obliged to take the corrective measures for elimination of the mistakes, and the Ministry of Health shall prohibit the laboratory to provide the laboratory services for which deviation of the results is established until their elimination.

(3) The laboratory shall be obliged to inform the Ministry of Health that it has acted upon the recommendations for elimination of the mistakes, upon which the Ministry of Health shall be obliged, within a period of 15 days as of the receipt of the information, to make an extraordinary control in terms of Article 245-b paragraph (3) of this Law, in a manner determined by the provisions of this Law regulating the regular external control.

(4) If the extraordinary external control referred to in paragraph (3) of this Article re-establishes the deviation of the values of the control sample, the laboratory shall be revoked the license for work for that kind of a test.

(5) If the laboratory which has been revoked the license in accordance with paragraph (4) of this Article continues to make that test, it shall be revoked the license for work for all the tests it makes.

**Revocation of a license for work**

**Article 245-j**

If the laboratory does not apply for a regular external control, does not take the control sample, does not make the test, and does not announce the result within the deadline set in Article 245-h paragraph (1) of this Law, it shall be deemed that the laboratory refuses the external control to be made, for which the laboratory shall be revoked the license for work.

**Good laboratory practice and operational work procedures**

**Article 245-k**

(1) In the course of carrying out the laboratory activity, the laboratories shall be obliged to apply the principles of good laboratory practice determined by the minister of health.

(2) The laboratories shall be obliged to establish written standard operational work procedures.

(3) The laboratories shall be obliged to authorize a person who shall be responsible for the quality of the services in the laboratory and for implementation of the standard operational procedures.

**4. Expert bodies**
Health Council

Article 246

(1) Health Council, composed of nine members, shall be formed in the Ministry of Health as an advisory body of the minister of health.

(2) Member of the Health Council may be a person who holds a university degree in the field of medicine, dental medicine, pharmacy, economy and law and has work experience in the field of health, considering the equitable representation of the citizens of all the communities.

(3) The scope and the manner of work of the Health Council shall be established by Rules of Procedure.

(4) The Health Council referred to in paragraph (1) of this Article, as well as the other permanent or temporary advisory bodies, depending on the needs of studying a particular issue or drafting laws and bylaws within the scope of work of the Ministry of Health, shall be formed by the minister of health.

Health Ethics Commission

Article 247

(1) Health Ethics Commission shall be formed within the Ministry of Health for studying and reviewing issues in the field of ethics and deontology in the field of health and for giving opinions and explanations upon particular ethical and deontological issues in the field of health, which shall be composed of experts in the field of medicine, pharmacy, health and obstetric care, psychology, law, sociology, human sciences and medical deontology.

(2) The Health Ethics Commission shall approve the proposals for scientific and research projects that include patients and shall carry out other activities, determined by this and another law.

(3) The Health Ethics Commission shall cooperate with the competent chambers, the healthcare institutions, the Health Council, and the higher education institutions in the field of medicine, dental medicine, that is, pharmacy.

(4) The composition, the manner of work, the procedure for appointment and dismissal, and the amount of the remuneration for the work of the members per session of the Ethics Commission held, shall be prescribed by the minister of health.

Coordinating body

Article 248

(1) A coordinating body, composed of representatives from the Ministry of Health, the Fund and the Doctors', Dental, that is, Pharmaceutical Chamber, shall be formed in the Ministry of Health for studying and reviewing issues related to the policies and the priorities in the health protection and health insurance, as well as for proposing opinions and views concerning the health services programs and the amount of funds necessary for their implementation.

(2) The manner of work of the coordinating body referred to in paragraph (1) of this Article shall be determined by Rules of Procedure.

Expert commissions
Article 249

(1) Other expert commissions may be formed within the Ministry of Health as expert and advisory bodies of the minister of health regarding particular types of healthcare activity, that is, specialty.

(2) The tasks of the expert commission shall particularly include:
- preparation of expert instructions for evidence-based medicine,
- preparation of expert views and analysis, and
- review of reports in the field of quality of health protection and safety in the performance of the healthcare activity.

(3) The minister of health shall determine the particular types of healthcare activity, that is, specialties for which expert commissions are formed which have to include all the specialties, and the general, that is, family medicine, healthcare and pharmaceutical activity.

(4) The expert commissions shall be formed by the minister of health.

(5) The number of members, the manner of appointment and dismissal, the manner of work, and the remuneration of the work of the expert commissions per completed task shall be determined by the minister of health, on a proposal of the expert associations.

XI. CHAMBER ASSOCIATION

Chambers

Article 250

(1) For the purpose of protecting and promoting the professionalism and the ethical duties and rights, improving the quality of health protection, protecting the interests of the profession, monitoring the behavior of the healthcare workers towards the society and the citizens, the doctors of medicine, the doctors of dental medicine and the graduated pharmacists shall join in the Doctors’, Dental, that is, Pharmaceutical Chamber of Macedonia.

(2) The healthcare workers with a high school, two-year post secondary school and higher vocational degree in the field of medicine, dental medicine and pharmacy shall also join in a chamber.

(3) The chambers referred to in paragraphs (1) and (2) of this Article shall adopt a statute, code of professional ethical duties and rights, shall form a court of honor and other assisting bodies.

Chambers as a legal entity

Article 251

(1) The chambers shall have the capacity of a legal entity and shall be entered in the Central Register of the Republic of Macedonia.

(2) In addition to the request for entry of the chamber in the register of chambers, the proposing party shall submit minutes from the founders’ assembly, a copy of the statute of the chamber, and a decision on appointment of a president of the chamber and a secretary, provided that the chamber has a secretary, and in the case of dissolution of the chamber, the proposing party shall attach a decision on dissolution of the chamber in accordance with the statute to the request.
(3) If the chamber amends the statute, elects or dismisses a president or if any of the data entered in the Central Register of the Republic of Macedonia are altered, it shall submit a request for amendment of the entry in the register within a period of 30 days as of the day of occurrence of the change.

(4) In addition to the request referred to in paragraph (3) of this Article, the chamber must submit minutes from the session of the assembly at which the amendments have been adopted.

Founders’ assembly

Article 252

(1) The statute of the chamber shall be adopted and its bodies shall be elected at the founders’ assembly of the chamber.

(2) The founders’ assembly of the chamber shall be convened by healthcare workers who want to establish a chamber.

(3) The decision on convening the founders’ assembly shall be published in the “Official Gazette of the Republic of Macedonia”.

(4) Anybody who may be a member of the chamber in accordance with the law and the draft statute and who registers his/her participation in the founders’ assembly within the deadline determined in the decision on convening referred to in paragraph (3) of this Article, may participate in the founders’ assembly.

Statute

Article 253

The statute of the chamber (hereinafter: the statute) shall contain provisions pertaining to:
- the name and the head office of the chamber,
- the aims and objectives of the chamber,
- the bodies of the chamber, the procedure for their election, that is, appointment, and the reasons and the manner of their dissolution, their composition, the competences and the manner of making decisions,
- the persons who represent the chamber in the legal transactions,
- the rights, obligations and responsibilities of the members of the chamber and their representatives in the chamber’s bodies,
- the manner of ensuring funds necessary for performance of the activities of the chamber,
- the manner and procedure for establishing the membership fee and parameters for its establishment,
- the activities of the chamber financed by the membership fee,
- the procedure for amendment of the statute of the chamber,
- the other general acts and the procedure for their adoption,
- the manner and the obligations of the member at joining and leaving the chamber, and
- other activities determined by this Law and by the statute.

Bodies

Article 254

(1) Bodies of the chamber shall be:
- assembly,
- executive board,
- supervisory board, and
- president of the chamber.

(2) The chamber may as well have other bodies, provided that it is determined by the statute.

**Assembly**

**Article 255**

(1) The assembly of the chamber shall be the highest body of the chamber.

(2) The assembly of the chamber may, in accordance with the statute, be composed of all of its members or of the elected representatives of the members.

(3) If the assembly of the chamber is composed of elected representatives of the members, the statute of the chamber shall regulate the manner of their election and the duration of their term of office in the assembly.

(4) Every member of the chamber shall have the right to participate in the election of the representatives of the members of the assembly.

**Activities of the assembly**

**Article 256**

(1) The assembly of the chamber shall particularly carry out the following activities:
   1) adopt a statute of the chamber;
   2) adopt the annual work program and the financial plan and the reports on their implementation;
   3) decide upon the amount of the membership fee; and
   4) decide upon the appointment and dismissal of the president of the chamber and of the members of the governing and supervisory board.

(2) The work program and the financial plan referred to in paragraph (1) point 2 of this Article shall determine the activities and the amount of funds of the chamber and the purpose of their use.

(3) The manner of convening and making decisions of the assembly shall be regulated by the statute.

**Executive board**

**Article 257**

(1) The executive board of the chamber shall particularly carry out the following activities:
   1) propose to the assembly to adopt a work program and a financial plan;
   2) review and adopt proposals concerning the materials for the sessions of the chamber's assembly;
   3) implement the work program and the financial plan and the other decisions of the assembly and notify the assembly thereof; and
   4) review proposals of the members concerning the actions of the chamber.

(2) The members of the executive board shall be elected for a period of four years at the most and may be re-elected for only one additional term.

(3) The number of members of the executive boards shall be determined by the statute.
Supervisory board

Article 258

(1) The number of members of the supervisory board shall be determined by the statute.

(2) Member of the supervisory board cannot be the president of the chamber, that is, the member of the executive board of the chamber.

(3) The term of office of the members of the supervisory board shall be four years at the most with the possibility to be re-elected for only one additional term.

(4) The president of the supervisory board shall be elected from among the members of the supervisory board, and he/she shall convene and chair the sessions of the supervisory board.

(5) The supervisory board shall supervise the lawfulness of the work and the regularity of the work of the chamber and it shall notify the assembly of the chamber about its work.

President and members of the boards

Article 259

(1) The person who meets the requirements set out by the statute may be elected a president of the chamber, a member of the executive board and of the supervisory board.

(2) Only a person who is a healthcare worker employed in an institution may be elected as president of the chamber.

(3) The president of the chamber shall represent the chamber in the legal transactions.

(4) The principle of equitable representation of all the communities in the Republic of Macedonia shall apply to the election of the chambers’ bodies.

Funds for work

Article 260

(1) The funds for work of the chamber shall be provided from the membership fee, the payments for the services provided by the chamber, donations and other sources.

(2) The chamber shall keep accountancy in accordance with the regulations in the corresponding field.

(3) The chamber shall guarantee for its obligations with all of its assets.

(4) The members of the chamber shall not be held liable for the obligations of the chamber.

Public authorizations and duties of the Doctors’, Dental, that is, Pharmaceutical Chamber

Article 261
(1) The Doctors', Dental, that is, Pharmaceutical Chamber shall issue, renew, extend and revoke licenses for work, shall keep a register of issued, renewed, extended and revoked licenses, and shall conduct expert supervision of the work of the healthcare institutions and the healthcare workers.

(2) The chambers referred to in paragraph (1) of this Article shall conduct expert supervision of the work of the healthcare workers on the basis of an annual plan for expert supervision of the work of the healthcare institutions and the healthcare workers, which shall be approved by the minister of health.

(3) The chambers referred to in paragraph (1) of this Article shall be obliged to adopt the annual plan for expert supervision no later than 31 December in the current year for the following year.

(4) The form and the contents of the registers referred to in paragraph (1) of this Article and the manner of their keeping shall be prescribed by the chambers referred to in paragraph (1) of this Article by an act approved by the minister of health.

(5) The chambers referred to in paragraph (1) shall determine a code of professional ethical duties and rights, shall establish a court of honor and other assisting bodies, and shall adopt other acts on the manner of operation of their bodies and other acts that they are authorized for by law.

(6) The chambers referred to in paragraph (1) of this Article shall be obliged, twice a year, to submit a report on the activities pertaining to the issuance, extension, renewal and revocation of the licenses for work to the Ministry of Health.

Public authorizations for carrying out the activities of the chamber

Article 262

(1) The chamber referred to in Article 250 paragraph (2) of this Law may, in accordance with this Law, be delegated public authorization for carrying out all or part of the following activities:
- issuance, renewal, extension and revocation of the license of healthcare workers,
- keeping a register of issued, renewed, extended and revoked licenses, and
- adoption of general acts in accordance with law, and with the consent of the minister of health.

(2) Each public authorization shall be delegated to the chambers for a period of five years.

(3) The minister of health shall delegate the public authorization by a decision.

Requirements for delegation a public authorization

Article 263

(1) The chamber referred to in Article 250 paragraph (2) of this Law may be delegated a public authorization if it meets the following requirements:
- acts in the field of ensuring expertise in a particular profession, that is, in the field it covers,
- acts on the territory of the entire country,
- has employed a sufficient number of workers who, in line with the regulations, are authorized for conducting an administrative procedure and other professional activities,
- has at its disposal an appropriate equipment for carrying out the activities under the public authorization, which shall ensure availability of the data and the records,
- a bankruptcy procedure, procedure of coercive settlement or liquidation has not been initiated against it,
- there are no circumstances that could lead to justified conclusion that the public authorization is not to be executed in accordance with the provisions of this Law, and
- it has not been revoked the public authorization in the last five years.
(2) The chambers referred to in Article 250 of this Law have to meet the requirements referred to in paragraph (1) of this Article during the entire duration of validity of the public authorization.

**Revocation of the public authorization**

**Article 264**

(1) The minister of health shall, *ex officio*, by a decision, revoke the public authorization of the chamber if he/she establishes:
- irregular, illegal and untimely performance of the activities under the public authorization,
- non-meeting of the requirements referred to in Article 263 paragraph (1) of this Law,
- giving false statements, data or documents in the procedure for obtaining the public authorization or during the control of the meeting of the requirements for obtaining the public authorization, and
- that the chamber has not eliminated the established faults and irregularities after the supervision referred to in Article 265 paragraph (1) of this Law within the time period set for their elimination.

(2) The minister of health may by a decision establish termination of the execution of the public authorization upon a request of the chamber, which shall also set the time period for termination of the execution of the public authorization.

(3) An appeal against the decision on revocation, that is, termination of the execution of the public authorization of the chamber shall not be allowed, but the dissatisfied party may initiate an administrative dispute.

(4) The decision on revocation, that is, termination of the execution of the public authorization shall be final and it shall be published in the “Official Gazette of the Republic of Macedonia”.

(5) As of the day of revocation, that is, termination of the execution of the public authorization, the administrative activities of a holder of public authorization shall be taken over by the Ministry of Health.

(6) The chamber that has been revoked or/and terminated the execution of the public authorization shall be obliged, within a period of 15 days as of the day the decision on revocation, that is, termination of the execution of the public authorization becomes final, to hand over to the Ministry of Health the entire documentation and the records it has and keeps concerning the execution of the public authorization in an electronic form and in writing.

**Supervision**

**Article 265**

(1) The Ministry of Health and the State Sanitary and Health Inspectorate shall supervise the lawfulness of the work of the chambers in the execution of the public authorization.

(2) After the supervision referred to in paragraph (1) of this Article, the Ministry of Health, that is, the State Sanitary and Health Inspectorate shall notify the chamber which has been supervised about the established faults and irregularities and shall set a time period for their elimination and if they are not eliminated, the minister of health shall revoke the public authorization.

(3) The Ministry of Health and the State Audit Office shall audit the material and financial operations of the chambers.

**Professional associations**
Article 266

(1) The healthcare workers in particular specialties may be associated in professional associations within the Macedonian Doctors’ Association, the Macedonian Dental Association, and the Macedonian Pharmaceutical Association and in other doctors’, dental and pharmaceutical associations, especially for the purpose of monitoring the achievements and improvements in particular branches of medicine, dental medicine, that is, pharmacy.

(2) The Macedonian Doctors’ Association, the Macedonian Dental Association, the Macedonian Pharmaceutical Association and the other doctors’, dental and pharmaceutical associations through the professional associations and through other professional associations shall organize different forms of professional development of healthcare workers, shall participate in the drafting of professional instructions for work in particular specialties, and shall propose measures for promotion of the professional work of healthcare workers.

(3) The healthcare workers with a high school, two-year post secondary school or higher vocational education in the field of medicine, dental medicine, and pharmacy may join in professional associations, through which they shall organize different forms of professional development of healthcare workers, shall draft professional instructions for work, and shall propose measures for promotion of the professional work of healthcare workers.

(4) The principle of equitable representation of all communities in the Republic of Macedonia shall apply to the election of the bodies of the professional associations.

XII. EXAMINATION OF DECEASED PERSONS AND AUTOPSY

Determination of the time and the reason of death and prohibition of burial prior to conducting an examination or autopsy

Article 267

(1) The time and the reason of death shall be established for each deceased person.

(2) No deceased person, that is, stillborn child cannot be buried before an examination or an autopsy is performed and the time and the reason of death is established.

Persons authorized for examination of deceased persons

Article 268

(1) The examination of deceased persons shall be performed by authorized persons and their deputies, appointed by the minister of health upon a proposal of a healthcare institution.

(2) Healthcare workers specialists in forensic medicine or pathology, healthcare workers with a degree from the faculty of medicine, holding a license for work, and successfully completed appropriate training for examination of deceased persons may be appointed for examination of deceased persons.

(3) The training for examination of deceased persons may be delivered by a specialist in the field of forensic medicine or pathology.

(4) The authorized healthcare worker cannot examine a deceased person he/she has previously treated.
(5) The number and the roster of the persons referred to in paragraph (1) of this Article shall be determined in a manner that ensures coverage of the entire territory of the Republic of Macedonia, and the persons shall be selected on the basis of fulfillment of the requirements referred to in paragraph (2) of this Article and the level of success achieved after the completion of the training for examination of deceased persons.

(6) The number and the roster of the persons referred to in paragraph (1) of this Article and the manner of selection shall be prescribed by the minister of health.

Monitoring the work of the authorized persons

Article 269

(1) The training for examination of deceased persons shall be delivered and the work of the authorized persons and their deputies shall be monitored by a higher education institution in the field of forensic medicine and pathology.

(2) The institution referred to in paragraph (1) of this Article shall, on the basis of the monitoring of the work of the authorized persons, give recommendations for the development and promotion of the manner and the methods of examination of deceased persons and the forensic and medical autopsy, and pathoanatomical autopsy.

Persons who died in healthcare institutions

Article 270

(1) The reason of death of the persons who died in healthcare institutions shall be established in a higher education institution in the field of forensic medicine and pathology.

(2) The death of each patient in the healthcare institution must be individually analyzed by the professional collegium of the institution where the patient has died.

(3) The medical documentation for the person referred to in paragraph (1) of this Article, including the opinion of the profesional collegium, as well as the finding of the specialist in forensic medicine or pathology of the completed autopsy, shall be mandatorily delivered to the Commission for Quality in the healthcare institution, within a period of seven days as of the day of death at the latest.

(4) The Commission referred to in paragraph (3) of this Article shall, once a month, mandatorily review the complete medical documentation, opinions and findings referred to in paragraph (3) of this Article.

(5) The commission referred to in paragraph (3) of this Article shall be obliged to deliver the opinion regarding the death of each patient individually to the Ministry of Health, no later than the end of the month following the month of the death.

(6) The form and the contents of the opinion form referred to in paragraph (5) of this Article shall be prescribed by the minister of health.

Duty to report a case of death or a case of a stillborn

Article 271
(1) The members of the family of the deceased person shall be obliged to immediately report the case of death or the case of a stillborn, and if there are no members of the family or they are unfamiliar with the case, the obligation shall be on any person who has found out about the case or has found the deceased person.

(2) The case of death or the case of a stillborn shall be reported to a person authorized for examination of deceased persons, that is, to the State Sanitary and Health Inspectorate and to the state administrative body responsible for internal affairs in the area where the person has died, that is, where the deceased person has been found.

**Examination of a deceased person**

**Article 272**

(1) As a rule, the examination of the deceased person shall be carried out 2 hours after the death at the earliest at the place of death, and 12 hours after the death is reported at the latest.

(2) After the completed examination of the deceased person, the authorized person shall issue a death certificate.

**Burial**

**Article 273**

(1) A deceased person shall be buried after the elapse of 24 hours as of the time of death.

(2) As an exception, on the basis of an approval of the State Sanitary and Health Inspectorate, the burial may take place before the expiry of 24 hours and after the expiry of 48 hours.

**Funds for examination of a deceased person and for expert determination of the time and reasons of death**

**Article 274**

The funds for examination of deceased persons and for delivery of particular trainings for examination of deceased persons shall be provided through a program adopted by the Government, upon a proposal of the Ministry of Health.

**Autopsy**

**Article 275**

(1) In case of suspicion or where it is obvious that it is not a natural death, the body of the deceased person shall undergo a forensic and medical autopsy, and forensic and medical expertise by two doctors of medicine, one of whom shall be a doctor of medicine – specialist in forensic medicine.

(2) Forensic and medical autopsy shall be carried out in the case of:
1) murder or suspected murder, that is, suicide or suspected suicide;
2) cremation of the deceased;
3) suspected medical mistake;
4) technological or ecological catastrophes;
5) special significance for protection of the citizens’ health, that is, where required by the epidemiological, sanitary and scientific and research reasons;
6) sudden death, where the reason of death is unknown, that is, it is not clear or is inexplicable in any other manner, including a sudden death of a baby and where the death is related to a diagnostic or therapeutic procedure;
7) death in custody, prison, upon the taking in by the police;
8) suspecting death as a consequence of torture or inhuman treatment;
9) police or military activity-related death;
10) unidentified or skeletonized bodies; and
11) where it is required by a member of the immediate family of the deceased person, the authorized healthcare worker who has treated the deceased person, or the person authorized for examination of deceased persons.

(3) The body of the person who died in a healthcare institution shall undergo pathoanatomical autopsy.

(4) In the cases referred to in paragraph (1) points 2, 5, 6 and 11 of this Article both pathoanatomical or forensic and medical autopsy may be carried out.

(5) An autopsy shall be carried out in cases of unnatural death or death of unknown origin, where the death occurs during diagnostic or therapeutic intervention, where the death occurs in a period of 24 hours after the admission of the person in the healthcare institution, where the person has been part of a clinical trial of a medicament or a medical device, that is, a scientific examination in the healthcare institution, or in cases of death of a person whose body parts may be harvested for the purpose of transplanting in accordance with law.

(6) The costs for the autopsy of the deceased shall be covered by the Fund, except in the cases where the autopsy is requested by a member of the family or of the competent bodies, where the costs of the autopsy shall be borne by them.

(7) The amount of the costs for the forensic and medical autopsy of the deceased shall be prescribed by the minister of health upon a previous opinion from the Court Budget Council.

(8) Parts removed from the human body in the healthcare institution due to therapeutic, diagnostic and esthetic purposes shall mandatorily undergo a histopathological analysis.

**Act of the minister of health**

**Article 276**

The manner of examination of deceased persons and the autopsy, the contents of the program and the manner of delivery of the training for persons authorized to examine deceased persons, as well as the form and the contents of the death certificate and the autopsy protocol, shall be prescribed by the minister of health, in accordance with the minister of interior.

**XIII. MARKETING AND ADVERTISING**

**Prohibited and allowed marketing**

**Article 277**

(1) Marketing in the mass media, marketing in other media conveying advertising and marketing messages, and marketing on the Internet of persons who treat or provide medical assistance without a prescribed professional degree shall be prohibited.
(2) Marketing the healthcare activity, that is, the healthcare institutions in a misleading, indecent manner or in a manner which makes comparisons with other healthcare activities or institutions shall be prohibited.

(3) Misleading marketing of the healthcare activity, that is, of the healthcare institutions, in terms of paragraph (2) of this Article, shall be the marketing which:
- in any manner, including as well the presentation of the healthcare workers, that is, the healthcare institution or the health services, may mislead the patients,
- uses or might use the patients for their inexperience, lack of information or lack of knowledge, for the purpose of gaining profit, or
- contains ambiguities, exaggerations or similar contents that mislead or might mislead.

(4) Indecent marketing of healthcare activity, that is, of healthcare institutions, in terms of paragraph (2) of this Article, shall be the marketing that contains offensive contents or contents that might be offensive or are contrary to the ethics.

(5) Marketing that compares healthcare activities or institutions, in terms of paragraph (2) of this Article, shall be the marketing of healthcare activity, that is, of healthcare institutions that might cause damage to the work of the other healthcare institutions or might have harmful effect on the choice of healthcare institution.

(6) Marketing, in terms of paragraph (1) of this Article, shall also be considered the publication of articles in the media for the purpose of promoting the healthcare activity, that is, promoting the healthcare workers, that is, the healthcare institutions, except the publication of articles with preventive contents for the public and publication of expert articles in professional magazines, books and publications, intended for informing the healthcare institutions, that is, the healthcare workers.

Marketing prohibition by a decision

Article 278

In case of marketing contrary to Article 277 of this Law, the Ministry of Health may prohibit such marketing and revoke the license for work of the healthcare institution.

Information of the public

Article 279

(1) The public may be informed about the performance of a healthcare activity of a particular healthcare institution by publishing the following data in the mass media or on the Internet:
- name and address of the healthcare institution,
- type of healthcare activity carried out in the network or outside the network,
- level of health protection, activity and specialty,
- training and qualifications of the healthcare workers,
- working hours of the healthcare institution,
- actual waiting time,
- price list of health services, and
- logo, that is, trademark of the healthcare institution.

(2) The data referred to in paragraph (1) lines 1, 2, 3 and 4 of this Article shall be published in accordance with the license for work of the institution.

(3) The information of the public referred to in paragraph (1) of this Article must not contain false contents.
Marking the facility where the healthcare activity is performed

Article 280

(1) The healthcare institution shall be obliged to display a sign, that is, a board on the facility where it performs the healthcare activity, which shall contain the following data:
- name and head office of the healthcare institution determined by the license for work,
- type of healthcare activity it performs,
- data whether the healthcare activity is performed within the network or outside the network,
- level of health protection, activity and specialty, and
- working hours of the healthcare institution.

(2) In addition to the data referred to in paragraph (1) of this Article, the sign, that is, the board of the facility may also contain a list of healthcare workers and their professional degree.

(3) The sign, that is, the board cannot contain false data.

(4) The manner of displaying the data, contents, look, size and form of the sign, that is, of the board referred to in paragraph (1) of this Article shall be prescribed by the minister of health.

XIV. PERFORMANCE OF HEALTHCARE ACTIVITY IN STATES OF EMERGENCY, CRISES AND STRIKE

Determination of the tasks for providing health protection in states of emergency and crises

Article 281

The Ministry of Health and the healthcare institutions shall be obliged to determine their tasks for provision of health protection in states of emergency and crises (natural and other serious disasters and states of emergency) in the general acts, in accordance with the law.

Provision of funds and personnel

Article 282

The Ministry of Health and the healthcare institutions shall be obliged to provide funds for stockpile of medicaments and sanitary materials, personnel and other necessities for work in states of emergency and crises.

Adjusting the work of the Ministry of Health and the healthcare institutions

Article 283

In states of emergency and crises, the Ministry of Health and the healthcare institutions shall be obliged to adjust their work, to take measures for unobstructed work and for elimination of the consequences from such state.
Cooperation between the Ministry of Health and the healthcare institutions with other entities

Article 284

In the course of planning the performance of the activities in states of emergency and crises, the Ministry of Health and the healthcare institutions shall cooperate with the representatives of the Center for Crisis Management and the Directorate for Protection and Rescue, the Red Cross of Macedonia and other state institutions and citizens’ associations.

Special competences of the Ministry of Health

Article 285

(1) In states of emergency and crises, the Ministry of Health may decide upon establishment of healthcare institutions in accordance with the needs.

(2) The Ministry of Health may give special assignments for the healthcare institutions and for the healthcare workers which, in regular circumstances, are not their activity, that is, assignment.

Right to strike

Article 286

The employees in the healthcare institutions may exercise the right to strike, provided that it does not jeopardize the life or health of the citizens seeking health protection.

Duties of the director during strike

Article 287

(1) For the purpose of eliminating the harmful consequences that may occur due to failure to provide health services during time of strike, the director of the healthcare institution shall be obliged to ensure emergency medical care and minimum operation of all organizational parts in the work process.

(2) Based on the taken measures referred to in paragraph (1) of this Article, the employees shall be obliged to act upon the respective orders.

(3) If the employees fail to act in accordance with paragraph (2) of this Article, the director shall be obliged to ensure the fulfillment of the working process by substituting appropriate profiles of employees.

(4) The employees referred to in paragraph (2) of this Article who fail to meet the working duties shall commit a more serious violation of the working discipline which shall be considered basis for termination of the employment.

Competence of the Government

Article 288
(1) If the healthcare institution fails to ensure implementation of the measures referred to in Article 287 of this Law, the Government as a temporary measure may:
- appoint an acting director in the public healthcare institution during the strike,
- provide appropriate personnel necessary for performance of those activities, and
- take measures for providing other conditions necessary for delivering healthcare activity for the needs of the citizens.

(2) The decisions adopted on the basis of paragraph (1) of this Article shall last until the termination of the conditions that have led to their introduction.

XV. OTHER PROVISIONS

Compensation paid upon production and import of tobacco products

Article 289

Deleted

Reimbursement of the compensation

Article 290

Deleted

Manner and procedure of establishing, calculating and paying

Article 291

Deleted

Records of persons obliged to pay compensations

Article 292

Deleted

Time barring of the obligation for payment

Article 293

Deleted

XVI. SUPERVISION

Definition of supervision

Article 294
(1) In order to ensure the application of this Law and the regulations adopted thereon, as well as to ensure the quality and safety in the provision of health protection when performing the healthcare activity, there shall be:

1) supervision of the lawfulness of the work;
2) supervision of the professional work;
3) internal supervision of the professional work; and
4) inspection.

(2) The healthcare institution and the other institutions performing healthcare activity shall be obliged to ensure unobstructed supervision as referred to in paragraph (1) of this Article and to provide the necessary assistance, data, documents and notifications necessary for conducting the supervision.

Supervision of the lawfulness of the work

Article 295

(1) The Ministry of Health shall supervise the lawfulness of the work of healthcare institutions.

(2) The Ministry of Health shall supervise the lawfulness of the work of healthcare institutions as a regular supervision in line with the annual program, and when necessary or upon a proposal of the Fund, the corresponding chamber, state body, association and citizen.

(3) The Ministry of Health shall supervise the lawfulness of the work of healthcare institutions referred to in paragraph (1) of this Article through a commission appointed by the minister of health.

(4) If faults, that is, irregularities are established in the healthcare institution during the supervision of the lawfulness, the minister of health shall adopt a decision on:
- determination of measures for elimination of the faults, that is, of the irregularities and deadlines for their implementation and
- abolished 46

(5) The costs for the supervision of the lawfulness whereby faults, that is, irregularities are established shall be covered by the healthcare institution wherein the faults, that is, the irregularities have been established.

Supervision of the professional work

Article 296

(1) The supervision of the professional work of the healthcare institutions and the other institutions that perform healthcare activity and of healthcare workers and co-workers shall be conducted for the purpose of controlling the professional work, the implementation of the professional instructions, assessment of the professional work, as well as assessment of the conditions and the manner of providing health protection.

(2) The Doctors', Dental, that is, Pharmaceutical Chamber shall conduct the supervision referred to in paragraph (1) of this Article.

(3) The supervision referred to in paragraph (1) of this Article shall be conducted as a regular professional supervision and as a professional supervision when necessary.

(4) The regular professional supervision shall be conducted in accordance with the annual plan referred to in Article 261 paragraph (2) of this Law.
(5) Supervision of the professional work when necessary shall be conducted upon a request of a patient, a member of his/her family, and a state body.

(6) The minister of health, when necessary, may form a commission for supervision of the professional work of the healthcare institutions and the other institutions performing healthcare activity and of the healthcare workers and co-workers.

**Report for completed professional supervision**

**Article 297**

(1) The competent chamber shall, within a period of eight days as of the day of completion of the supervision of the professional work, submit a report on the supervision to the minister of health and to the institution wherein the supervision has been conducted.

(2) The report shall mandatorily contain the following elements:
   - the established condition,
   - the possible faults, irregularities or omissions in the performance of the professional work, and particularly concerning the implementation of the professional instructions and the conditions and the manner of providing health protection,
   - professional opinion about the condition in the institution and the occurred or the possible consequences for the human health, and
   - proposal for determination of measures for elimination of the faults, irregularities or omissions and deadlines for their implementation.

(3) The institution wherein the supervision has been conducted, that is, the healthcare workers and co-workers covered by the supervision may file a complaint against the report of the completed supervision to the minister of health within a period of three days as of the day of receipt of the report in the institution.

(4) As an exception to paragraph (1) of this Article, if the competent chamber establishes an immediate risk upon the citizens’ life and health, it shall notify the minister of health thereof within a period of 24 hours at the latest and it shall propose taking appropriate measures.

**Decision of the minister of health upon the report on the completed professional supervision**

**Article 298**

(1) After reviewing the report referred to in Article 297, as well as the possible complaint filed as referred to in Article 297 paragraph (3) of this Law, the minister of health shall adopt a decision on:
   1) temporary prohibition for complete or partial performance of a certain type of healthcare activity;
   2) temporary prohibition for complete or partial work of the organizational unit of the institution;
   3) temporary prohibition for work of the healthcare institution; and
   4) abolished

(2) After reviewing the report referred to in Article 297, as well as the possible complaint filed as referred to in Article 297 paragraph (3) of this Law, the minister of health may:
   1) propose the competent chamber to initiate a procedure for revocation of the license for work of a healthcare worker;
   2) propose the healthcare institution to conduct a procedure for transfer to another job and/or sending to additional professional development, that is, assigning a mentor for the healthcare worker being established as insufficiently trained (qualified) and it shall notify the competent chamber for the activities taken; and
   3) initiate inspection by a competent body.
(3) The temporary prohibition to work referred to in paragraph (1) points 1, 2 and 3 of this Article shall last until the elimination of the reasons for which the prohibition has been imposed.

**Internal supervision of the professional work**

**Article 299**

(1) The healthcare institution shall be obliged to organize internal supervision of the professional work of the healthcare workers and co-workers in accordance with the provisions of this Law pertaining to the monitoring and the promotion of the quality of health protection in the performance of the healthcare activity.

(2) The director of the institution shall be responsible for the professional work of the healthcare institutions and the other institutions performing healthcare activity.

**Inspection**

**Article 300**

(1) Inspection of the application of this Law shall be conducted by the State Sanitary and Health Inspectorate, in accordance with this and another law.

(2) In accordance with law, for the purpose of eliminating the established irregularities, the state sanitary and health inspector (hereinafter: the inspector) shall have the right and obligation in respect of the entity under supervision to:

- point out the established irregularities and to determine a deadline for their elimination,
- file a motion for initiation of a misdemeanor procedure, and
- file criminal charges or to initiate another appropriate procedure.

(3) For the purpose of eliminating the established irregularities, the inspector may also act under other authorizations and duties in accordance with the law.

**Authorizations of the inspector**

**Article 301**

(1) In the course of conducting the inspection, the inspector shall be authorized to:

1) prohibit performance of the activity, as well as to prohibit use of the facility where the activity is performed, if there is no license for work, that is, if any of the requirements for performance of the activity are not met;

2) order establishment and keeping of the records prescribed by this Law and the regulations adopted on the basis of this Law;

3) order elimination of faults, that is, irregularities in accordance with the laws and the other regulations on protection of the human health; and

4) order reports to be prepared which the institution is obliged to submit to the Ministry of Health.

(2) The measures referred to in paragraph (1) of this Article shall be ordered by the inspector by a decision.

(3) An appeal against the decision of the inspector may be filed within a period of eight days as of the day of receipt of the decision.

(4) The State Commission for Decision-making in Administrative Procedure and Labor Relations Procedure in Second Instance shall decide upon the appeal against the decisions of the inspector.
(5) The appeal against the decision referred to in paragraph (2) of this Article shall not postpone its enforcement.

**Actions of the inspector**

**Article 302**

The provisions of the other laws referring to the inspection of the inspectorate referred to in Article 300 of this Law shall apply to the procedure for inspection, unless otherwise regulated by this Law.

**Oral order of the inspector**

**Article 303**

(1) Where the existence of immediate risk upon human life and health is established, the inspector shall issue an oral order for urgent and immediate elimination of the irregularities, which is put in minutes.

(2) In the cases referred to in paragraph (1) of this Article, the inspector shall adopt a decision within a period of 24 hours after the oral order is issued.

**Education**

**Article 304**

(1) If, during the conducting of the inspection, the inspector establishes that an irregularity as referred to in Articles 308 paragraph (1) points 9, 10, 16, 17 and 18, 309 paragraph (1) points 9, 10 and 11, 310 paragraph (1) point 3 and 311 paragraph (1) point 3 of this Law has been committed for the first time, he/she shall be obliged to prepare minutes to establish the committed irregularity by pointing to its elimination within a certain period and at the same time handing over an invitation for delivery of education of the person or legal entity where the irregularity has been established during the conducting of the inspection.

(2) The form and the contents of the invitation for education, as well as the manner of delivery of the education shall be prescribed by the minister of health.

(3) The education shall be organized and delivered by the State Sanitary and Health Inspectorate that has completed the inspection, within a period not longer than eight days as of the day of conducting the inspection.

(4) The education may be delivered for several identical, or of the same type, irregularities for one or several persons, that is, for one or several legal entities.

(5) If the person or the legal entity to be educated does not appear at the education, it shall be considered that the education is delivered.

(6) If the person or the legal entity to be educated appears at the scheduled education and completes it, it shall be considered educated regarding the established irregularity.

(7) If, during the conducting of the supervision, the State Sanitary and Health Inspectorate establishes that the established irregularities referred to in paragraph (1) of this Article have been eliminated, it shall adopt a decision on termination of the inspection procedure.
(8) If the State Sanitary and Health Inspectorate, during the conducting of the supervision, establishes that the established irregularities referred to in paragraph (1) of this Article have not been eliminated, it shall file a motion for initiation of a misdemeanor procedure before a competent body.

(9) The State Sanitary and Health Inspectorate that has completed the inspection shall keep records of the delivered education in a manner prescribed by the minister heading the state administrative body that has organized and delivered the education.

**XVI-a. PENALTY PROVISIONS**

**Rendering health services without a license for work**

**Article 304-a**

A healthcare worker, that is, co-worker who renders health services in premises for which he/she has no license for work, shall be held criminally liable and shall be sentenced to imprisonment of at least four years.

**Disclosure of a business secret**

**Article 304-b**

The responsible person in the legal entity producer of the samples which has been awarded the procurement contract in accordance with Article 245-f paragraph (2) of this Law, which does not keep the values of the control sample as a business secret and makes them available to the laboratory before it makes the test for the external control of the laboratory services, shall be criminally liable and shall be sentenced to imprisonment of at least two years.

**XVII. MISDEMEANOR PROVISIONS**

**Article 305**

(1) Fine in the amount of Euro 4,000 to 6,000 in Denar counter-value shall be imposed for a misdemeanor on a legal entity if it:

1) performs additional activity contrary to Articles 222 and 223 of this Law;
2) does not keep an electronic list of scheduled examinations and interventions and/or does not keep the electronic list of scheduled examinations and interventions in accordance with the criteria established in Article 39 of this Law;
3) does not keep the electronic list of scheduled examinations and interventions in a form of web application in accordance with Article 39 paragraph (2) of this Law;
4) does not publish the electronic list of scheduled examinations and interventions on the website and does not publish it on a daily basis in a visible place especially determined for that purpose in the premises of the institution in accordance with Article 39 paragraph (4) of this Law;
5) does not update the electronic list of scheduled examinations and interventions on a daily basis by 15.00 o’clock at the latest in accordance with Article 39 paragraph (4) of this Law;
6) does not assign at least two persons to keep, publish and update the electronic list of scheduled examinations and interventions in accordance with Article 39 paragraph (5) of this Law; and
7) does not publish the personal data of the patients contained in the electronic list of scheduled examinations and interventions as coded data in accordance with Article 39 paragraph (6) of this Law.

(2) Fine in the amount of Euro 4,000 to 6,000 in Denar counter-value shall be imposed on the responsible person in the legal entity for the misdemeanor referred to in paragraph (1) line 1 of this Article.
(3) Fine in the amount of Euro 4,000 to 6,000 in Denar counter-value shall also be imposed on the healthcare worker for the misdemeanor referred to in paragraph (1) line 1 of this Article.

(4) Fine in the amount of Euro 1,000 to 1,500 in Denar counter-value shall also be imposed on the responsible person in the legal entity for the misdemeanor referred to in paragraph (1) lines 2, 3, 4, 5, 6 and 7 of this Article.

(5) Fine in the amount of Euro 800 to 1,000 in Denar counter-value shall also be imposed on the responsible person who keeps, publishes and updates the electronic list of scheduled examinations and interventions for the misdemeanor referred to in paragraph (1) lines 2, 3, 4, 5 and 7 of this Article.

(6) In the case of repeating the misdemeanor referred to in paragraph (5) of this Article, the responsible person shall be imposed a fine in the amount of Euro 1,000 to 1,300 in Denar counter-value, and if the same misdemeanor is repeated for the third time, the responsible person who keeps, publishes and updates the electronic list of scheduled examinations and interventions shall be disciplinary liable and shall be imposed a disciplinary measure termination of employment.

(7) Fine in the amount of Euro 3,000 to 4,000 in Denar counter-value shall be imposed for a misdemeanor on the director of the healthcare institution in the case of failing to act upon the instructions within the deadline referred to in Article 110 paragraph (5), that is, paragraph (8) of this Law.

(8) Fine in the amount of Euro 3,000 to 4,000 in Denar counter-value shall be imposed for a misdemeanor on the director of the healthcare institution if he/she introduces continuous on-duty work without the consent from the Ministry of Health in accordance with Article 211 paragraph (6) of this Law.

Article 306

(1) Fine in the amount of Euro 3,000 to 6,000 in Denar counter-value shall be imposed for a misdemeanor on a legal entity if it:
1) as a healthcare institution in the network, introduces a new health technology and equipment without previous approval from the Ministry of Health (Article 17 paragraph (7));
2) performs a healthcare activity in the network with patients who cover the health services by their own funds contrary to Article 44 of this Law;
3) is established, starts operating, performs a healthcare activity and expands the activity contrary to Article 60 of this Law;
4) performs a healthcare activity without a license for work (Article 63 paragraph (1));
5) does not organize and harmonize the performance of the healthcare activity at primary level for the citizens in the area where it is established and/or, as a public healthcare institution or license holder in the network, does not participate in the performance of the healthcare activity at primary level (Article 213 paragraph (1));
6) fails to act in accordance with Article 213 paragraphs (2) and (3) of this Law in states of crises and states of emergency;
7) issues, renews or temporarily extends a license for work in the case where the requirements referred to in Articles 124, 129 and 130 of this Law are not met;
8) does not temporarily revoke the license for work of a healthcare worker with a university degree, in accordance with Article 130 paragraph (2) of this Law;
9) does not conclude an agreement with the resident in accordance with Article 147 of this Law;
10) does not ensure uninterrupted performance of the healthcare activity in the network (Article 211 paragraph (1));
11) does not keep the written report and/or the records of the incurred costs for three years as of the day of their submission (Article 224 paragraph (4));
12) does not provide health protection to a patient who seeks such protection (Article 225 paragraph (1));
13) does not ensure conditions for providing continuous medical care within a period of 24 hours
and/or does not have medicaments and sanitary materials for provision of emergency medical care (Article 225 paragraph (2));
14) does not organize an appropriate transport and medical care until the admission in the healthcare institution to a patient who needs to be referred to another healthcare institution (Article 225 paragraph (4));
15) does not admit the patient for a hospital treatment and/or does not ensure admission in another healthcare institution, except if the case is not urgent or the admission is not necessary upon the assessment of the authorized doctor (Article 226 paragraph (1));
16) does not issue the patient a written explanation of the reasons for rejection of the admission for hospital treatment (Article 226 paragraph (2));
17) as a healthcare institution, does not ensure performance of a healthcare activity in states of emergency and in the case of a strike (Articles 281 to 287); and
18) does not organize internal supervision of the professional work of the healthcare workers and co-workers in accordance with the provisions of this Law pertaining to the monitoring and promotion of the quality of the health protection in the performance of the healthcare activity (Article 299 paragraph (1)).

(2) Fine in the amount of Euro 1.500 to 3.000 in Denar counter-value shall also be imposed on the responsible person in the legal entity for the misdemeanor referred to in paragraph (1) of this Article.

(3) Fine in the amount of up to ten times the amount referred to in paragraph (1) of this Article shall be imposed for a misdemeanor on the legal entity if the misdemeanor referred to in paragraph (1) of this Article causes serious consequences upon the human safety, life and health or it obtains greater property benefit or causes greater property damage to other legal entities and natural persons.

(4) Fine in the amount of up to double the amount referred to in paragraph (1) of this Article shall be imposed for a misdemeanor on the responsible person in the legal entity if the misdemeanor referred to in paragraph (1) of this Article is perpetrated out of cupidity.

(5) The perpetrator of the misdemeanor referred to in paragraph (1) points 1, 2, 3, 4 and 12 of this Article, in addition to the imposed fine, shall also be imposed an administrative measure prohibition on performing a healthcare activity for a period of 30 days.

Article 307

(1) Fine in the amount of Euro 2.500 to 5.000 in Denar counter-value shall be imposed for a misdemeanor on a legal entity if:
1) as a healthcare institution in the network at primary level, does not cooperate with the healthcare institutions at secondary and tertiary level and/or with other entities (Article 41);
2) as a healthcare institution in the network at secondary level, fails to regulate, by an agreement, the mutual cooperation with another healthcare institution in the network at secondary level in the provision of emergency medical care and on-duty work, the provision of services in accordance with the distribution of the performance of the healthcare activity and the use of mutual diagnostic and other capacities, and other forms of cooperation (Article 42 paragraph (1));
3) as a healthcare institution in the network at secondary level, when releasing the patient from the hospital, does not cooperate with other institutions, if it is necessary (Article 43 paragraph (1));
4) as a hospital or a healthcare institution in the network at secondary level, does not ensure the chosen doctors in its area of operation advising via telephone or other manner of professional advising for complex expert matters within a period of 24 hours at the most (Article 43 paragraph (2));
5) does not submit a report and/or twice a year does not submit a report on the load and type of provided health services for the patients who cover the services by their own funds to the Ministry of Health (Article 44 paragraph (5));
6) does not keep separate records of the health services provided to patients who cover the services by their own funds (Article 45 paragraph (1));
7) does not use the surplus of the income over the expenditures gained by the healthcare institutions in the network by providing a healthcare activity for development of the health services and the healthcare activity (Article 45 paragraph (2));
8) does not keep the register of healthcare workers (Article 116 paragraph (1));
9) does not enter the data in the register of healthcare workers (Article 116 paragraph (2));
10) makes possible for the healthcare workers and the healthcare co-workers with a university degree to take an expert exam after the expiry of the period of one year as of the day of completion of the plan and the program for probationary work without to do their probationary work again (Article 121 paragraph (2));
11) does not define the program for additional training and examination of the expert knowledge and skills of the healthcare workers with a university degree, the composition of the examination commission and the manner of conducting the check (Article 127 paragraph (1));
12) does not insure the liability of the healthcare workers for the damage they might cause in the performance of the healthcare activity (Article 152 paragraph (2));
13) does not determine the longest acceptable time for arriving to work in the case of engaged on call (Article 218 paragraph (3));
14) makes possible for a healthcare worker to perform an additional activity contrary to Articles 222 and 223 of this Law;
15) does not apply the principles of good laboratory practice (Article 245-k paragraph (1));
16) does not establish written standard operational work procedures (Article 245-k paragraph (2));
17) does not authorize a person who is responsible for the quality of the services in the laboratory and for implementation of the standard operational procedures (Article 245-k paragraph (3));
18) does not adopt the annual plan for professional supervision no later than 31 December in the current year for the following year (Article 261 paragraph (3));
19) markets, that is, advertises the healthcare activity contrary to Article 277 of this Law; and
20) markets contrary to the marketing prohibition (Article 278).

(2) Fine in the amount of Euro 1.000 to 2.000 in Denar counter-value shall also be imposed on the responsible person in the legal entity for the misdemeanor referred to paragraph (1) of this Article.

(3) Fine in the amount of Euro 20.000 to 25.000 in Denar counter-value shall be imposed for a misdemeanor on the legal entity if it markets, that is, advertises the healthcare activity contrary to Article 277 of this Law.

(4) In the case of repeating the misdemeanor referred to in paragraph (3) of this Article, the Ministry of Health shall revoke the working license of the legal entity.

(5) Fine in the amount of Euro 3.000 to 5.000 in Denar counter-value shall also be imposed on the responsible person in the legal entity for the misdemeanor referred to in paragraph (3) of this Article.

**Article 308**

(1) Fine in the amount of Euro 1.500 to 3.000 in Denar counter-value shall be imposed for a misdemeanor on the legal entity if it:
1) does not issue a fiscal receipt for the provided health service to the patients who cover the services by their own funds (Article 47 paragraph (3));
2) at least six months before the termination of the work, does not notify the Ministry of Health and the beneficiaries of the health services (Article 61 paragraph (2));
3) does not assign educators under whose supervision the probationary work of the healthcare workers with university degree is conducted where the trainee period is done (Article 120 paragraph (1));
4) does not regulate by a general act the issues referred to in Article 129 paragraph (3) of this Law;
5) does not establish the manner of issuing, extending, renewing and revoking the license for work and the form and contents of the license for work form of the healthcare workers (Article 135);
6) does not determine the costs for issuance, extension and renewal of the license for work (Article 136 paragraphs (3) and (4));
7) does not make possible for a healthcare worker who has turned 57 for a woman and 59 for a man to exercise the right not to do on-duty work (Article 217 paragraph (1));
8) does not implement internal monitoring and promotion of the quality of the health protection in the performance of the healthcare activity and of the work of the healthcare workers and the healthcare
co-workers on the basis of an annual program for monitoring and promotion of the quality (Article 235 paragraph (1));
9) does not form a Commission for Monitoring and Promotion of the Quality of the Health Protection (Article 235 paragraph (2));
10) does not submit the annual program to the Ministry of Health no later than the 31st of December in the current year for the following year (Article 235 paragraph (3));
11) does not submit the annual reports for implementation of the activities determined by the program for monitoring and promotion of the quality of the health protection to the Agency for Quality and Accreditation (Article 238);
12) does not report each change concerning the accreditation to the Agency (Article 244 paragraph (5));
13) does not act in accordance with Article 270 paragraphs (2), (3) and (4) of this Law;
14) the Commission for Quality does not submit the opinion on the death of each patient individually to the Ministry of Health, no later than the end of the month following the month when the death has occurred (Article 270 paragraph (5));
15) informs the public about the performance of the healthcare activity contrary to Article 279 of this Law;
16) does not display on the facility where it performs the healthcare activity a sign, that is, a board and/or the sign, that is, the board does not contain the necessary data (Article 280 paragraph (1)); and
17) the sign, that is, the board contains false data (Article 280 paragraph (3)).

(2) Fine in the amount of Euro 500 to 1.000 in Denar counter-value shall also be imposed on the responsible person in the legal entity for the misdemeanor referred to in paragraph (1) of this Article.

**Article 309**

Fine in the amount of Euro 500 to 1.000 in Denar counter-value shall be imposed for a misdemeanor on a healthcare worker with a university degree if he/she:
1) independently provides health services contrary to Article 115 paragraph (1) of this Law;
2) does not keep records of the trainee period and does not ensure the implementation of the plan and program for probationary work (Article 119 paragraph (2));
3) as a resident provides, that is, performs particular activities within the provision of the health protection in the field of specialization, that is, subspecialization without the supervision of the educator (Article 144 paragraph (2));
4) as an educator, he/she makes possible for a resident to provide, that is, to perform particular activities in the provision of health protection in the field of specialization, that is, subspecialization without his/her supervision (Article 144 paragraph (2));
5) leaves his/her work after the end of the working hours without being substituted, if that would pose a threat to the patients’ health (Article 211 paragraph (4));
6) is not available in a manner and under the conditions referred to in Article 218 paragraph (1) of this Law;
7) does not draw up a written report for the provided health service as an additional activity for each patient (Article 224 paragraph (1));
8) does not separately procure medicaments, medical devices and expendables for the needs of the additional activity (Article 224 paragraph (2));
9) does not submit a copy of the written report and collective records of the incurred costs in accordance with the procurement of medicaments, medical devices and expendables to the public healthcare institution that carries out a healthcare activity where the additional activity has been performed (Article 224 paragraph (3));
10) does not participate in the implementation of the annual program for monitoring and promotion of the quality of the health protection (Article 235 paragraph (4));
11) as an authorized healthcare worker for examination of deceased persons, examines a deceased person he/she has treated immediately before the death (Article 268 paragraph (4));
12) as an authorized healthcare worker for examination of deceased persons, examines a deceased person 12 hours after the death is reported (Article 272 paragraph (1)); and
13) as a healthcare worker authorized for examination of deceased persons, does not issue a death certificate after the completed examination of a deceased person (Article 272 paragraph (2)).
Article 310

Fine in the amount of Euro 500 to 1.000 in Denar counter-value shall be imposed for a misdemeanor on a healthcare worker with a high school, two-year post secondary school and higher vocational education if he/she:
1) individually provides health services contrary to Article 115 paragraph (2) of this Law;
2) is not available in a manner and under the conditions referred to in Article 218 paragraph (1) of this Law; and
3) does not participate in the implementation of the annual program for monitoring and promotion of the quality of the health protection (Article 235 paragraph (4)).

Article 311

Fine in the amount of Euro 500 to 1.000 in Denar counter-value shall be imposed for misdemeanor on a healthcare worker with a university degree if he/she:
1) individually performs particular activities in the provision of healthcare activity contrary to Article 115 paragraph (4) of this Law;
2) is not available in a manner and under the conditions referred to in Article 218 paragraph (1) of this Law; and
3) does not participate in the implementation of the annual program for monitoring and promotion of the quality of the health protection (Article 235 paragraph (4)).

Article 312

(1) Fine in the amount of Euro 1.000 to 2.000 in Denar counter-value shall be imposed for a misdemeanor on healthcare workers, that is, healthcare co-workers who are consultants and advisors, individually or in a group, for provision of services as speakers or chairmen at meetings, participation in medical/scientific studies, clinical trials or services for training, participation in advisory meetings and participation in market research, where such participation includes remuneration and/or traveling without being previously regulated by a written agreement with the parties ordering the services (Article 168 paragraph (2)).

(2) Fine in the amount of Euro 1.000 to 2.000 in Denar counter-value shall be imposed for a misdemeanor on a healthcare worker, that is, a healthcare co-worker who accepts donation or sponsorship without prior consent from the Ministry of Health (Article 170 paragraph (3)).

(3) Fine in the amount of Euro 500 to 1.000 in Denar counter-value shall be imposed for a misdemeanor on a natural person in the case of failure to immediately report the case of death or a stillborn (Article 271).

(4) Fine in the amount of Euro 8.000 to 12.000 in Denar counter-value shall be imposed for a misdemeanor on the healthcare institution if a healthcare worker, that is, a healthcare co-worker who is not listed in the license for of the healthcare institution works there.

(5) Fine in the amount of Euro 5.000 to 9.000 in Denar counter-value shall also be imposed on the responsible person in the healthcare institution for the misdemeanor referred to in paragraph (4) of this Article.

(6) Fine in the amount of Euro 8.000 to 12.000 in Denar counter-value shall also be imposed on the healthcare worker, that is, the healthcare co-worker for the misdemeanor referred to in paragraph (4) of this Article.

(7) Fine in the amount of Euro 500 to 800 in Denar counter-value shall be imposed on the medical director if he/she does not determine a calendar of free terms pursuant to Article 39-a paragraph (2) of this Law.
(8) Fine in the amount of Euro 1,500 to 2,500 in Denar counter-value shall be imposed on the medical director if he/she does not establish the longest period of duration of the surgical intervention pursuant to Article 39-a paragraph (6) of this Law.

(9) Fine in the amount of Euro 500 to 800 in Denar counter-value shall be imposed on the director of the healthcare institution if, within a period of one day as of the submission of the request of the patient, does not compensate the travel costs pursuant to Article 39-a paragraph (10) of this Law.

(10) Fine in the amount of Euro 500 to 800 in Denar counter-value shall be imposed on the director of the healthcare institution if he/she does not provide constant internet connection pursuant to Article 39 paragraphs (12), (13), and (14) of this Law.

(11) Fine in the amount of Euro 1,800 to 2,200 in Denar counter-value shall be imposed on the legal entity if it fails to organize a healthcare point as an internal organizational unit pursuant to Article 96 paragraphs (3), (4), and (5) of this Law.

(12) Fine in the amount of Euro 500 to 800 in Denar counter-value shall be imposed on the responsible person in the legal entity if it does not organize a healthcare point as an internal organizational unit pursuant to Article 96 paragraphs (3), (4), and (5) of this Law.

(13) Fine in the amount of Euro 5,000 to 9,000 in Denar counter-value shall be imposed on the responsible person in the legal entity if it does not conclude an agreement under the same conditions with a private healthcare institution which requests conclusion of an agreement pursuant to Article 222 paragraph (15) of this Law.

(14) Fine in the amount of Euro 1,500 to 3,000 in Denar counter-value shall be imposed for a misdemeanor on the healthcare worker, that is, the healthcare co-worker employed in a public healthcare institution who has attended a professional training and/or professional development abroad if he/she does not make a presentation of the new healthcare method or procedure, that is, of the knowledge, capacities and skills gained during the professional training and/or professional development, in accordance with Article 170-a paragraph (1) of this Law.

(15) Fine in the amount of Euro 3,000 to 5,000 in Denar counter-value shall be imposed for a misdemeanor on the responsible person in the public healthcare institution where the healthcare worker, that is, the healthcare co-worker who has attended a professional training and/or professional development abroad is employed if he/she does not act in accordance with Article 170-a paragraph (2) of this Law.

(16) Fine in the amount of Euro 7,000 to 10,000 in Denar counter-value shall be imposed for a misdemeanor on the director of the public healthcare institution at tertiary level if he/she does not act in accordance with Articles 179-a paragraph (10), 179-b paragraph (6) and 179-c paragraph (3) of this Law.

(17) Fine in the amount of Euro 10,000 to 15,000 in Denar counter-value shall be imposed for a misdemeanor on the minister of health if he/she does not act in accordance with Articles 179-a paragraph (11), 179-b paragraph (7) and 179-c paragraph (4) of this Law.

(18) Fine in the amount of Euro 1,000 to 1,500 in Denar counter-value shall be imposed for a misdemeanor on the director of the public healthcare institution at secondary and tertiary level that carries out a hospital healthcare activity in the field of surgery if a procedure for approval of the plans for surgical intervention in accordance with Article 226-i of this Law is not conducted.

(19) Fine in the amount of Euro 1,000 to 2,000 in Denar counter-value shall be imposed for a misdemeanor on the legal entity producer of control samples which has been awarded the procurement contract and the responsible person in this legal entity if no analysis of the results of the control in accordance with Article 245-c paragraph (4) of this Law is made.
(20) Fine in the amount of Euro 3,000 to 5,000 in Denar counter-value shall be imposed for a misdemeanor on the legal entity producer of control samples which has been awarded the procurement contract and the responsible person in this legal entity if he/she does not keep the values of the control sample as a business secret in accordance with Article 245-f paragraph (2) of this Law and if he/she makes them available to the laboratory before it processes the control sample.

(21) Fine in the amount of Euro 3,000 to 5,000 in Denar counter-value shall be imposed for a misdemeanor on the laboratory and the responsible person in the laboratory if, at the beginning of the year, it does not apply to the Ministry of Health by submitting a list of all analyses for which the laboratory is registered in accordance with Article 245-e paragraph (2) of this Law.

(22) Fine in the amount of Euro 1,000 to 1,500 in Denar counter-value shall be imposed for a misdemeanor on the minister of health and on the legal entity producer of control samples which has been awarded the procurement contract and on the responsible person in this legal entity if he/she does not keep the data on the identification number of the laboratory and the code of the control sample as a business secret in accordance with Article 245-g paragraph (5) of this Law.

(23) Fine in the amount of Euro 3,000 to 5,000 in Denar counter-value shall be imposed for a misdemeanor on the laboratory and on the responsible person in the laboratory if they do not act in accordance with Article 245-h paragraph (1) of this Law.

(24) Fine in the amount of Euro 3,000 to 5,000 in Denar counter-value shall be imposed for a misdemeanor on the legal entity producer of control samples which has been awarded the procurement contract and on the responsible person in this legal entity if he/she does not act in accordance with Article 245-h paragraphs (4) and (5) and 245-j of this Law.

(25) Fine in the amount of Euro 15,000 to 20,000 in Denar counter-value shall be imposed for a misdemeanor on the laboratory which has been revoked the license in accordance with Article 245-i paragraph (4) of this Law if it continues to make the tests for which it has been revoked the license contrary to Article 245-i paragraph (4).

(26) Fine in the amount of Euro 2,500 to 5,000 in Denar counter-value shall be imposed for a misdemeanor on the responsible person in the laboratory which has been revoked the license in accordance with Article 245-i paragraph (4) of this Law if it continues to make the tests for which it has been revoked the license contrary to Article 245-i paragraph (4).

(27) Fine in the amount of Euro 5,000 to 6,000 in Denar counter-value shall be imposed for a misdemeanor on the authorized legal entity which implements technically the examination referred to in Article 106-c of this Law if it does not record the examination, does not live-stream it on the website of the Ministry of Health, and if it does not post the recording of the whole examination on the website of the Ministry of Health in accordance with Article 106-d paragraph (2) of this Law.

(28) Fine in the amount of Euro 1,000 to 1,500 in Denar counter-value shall be imposed for a misdemeanor on the representatives referred to in Article 106-d paragraph (4) of this Law if they act contrary to Article 106-e paragraph (9) of this Law.

(29) Fine in the amount of Euro 5,000 to 6,000 in Denar counter-value shall be imposed for a misdemeanor on the authorized legal entity that conducts the examination referred to in Article 106-c of this Law if it does not discontinue the examination in accordance with Article 106-e paragraphs (5) and (6) of this Law.

(30) Fine in the amount of Euro 1,000 to 1,500 in Denar counter-value shall be imposed on the minister of health if he/she does not adopt the decision within the deadline referred to in Article 106-k paragraph (7) of this Law.
(31) Fine in the amount of Euro 1.000 to 1.500 in Denar counter-value shall be imposed for a misdemeanor on the member of the expert commission for cancer referred to in Article 226-b paragraphs (3) and (4) of this Law if they do not keep the information presented at the meetings as a business secret in accordance with Article 226-d paragraph (6) of this Law.

(32) Fine in the amount of Euro 1.000 to 1.500 in Denar counter-value shall be imposed for a misdemeanor on the member of the expert commission for cancer referred to in Article 226-b paragraphs (3) and (4) of this Law if, after the discussion about each of the cases separately, the expert commission for cancer does not prepare a report containing the joint findings, conclusions and recommendations for the further treatment, it is not signed by all the members of the commission, and the report is not entered in the medical file of the patient in accordance with Article 226-h of this Law.

Article 313

(1) Fine in the amount of Euro 200 in Denar counter-value in the on-the-spot procedure shall be imposed for a misdemeanor on a healthcare worker if he/she:

1) disables, obstructs or hinders the use of the health service;
2) neglects the ill person who is in for hospital treatment;
3) does not abide by the general act on use of the work and protective clothes;
4) does not abide by the working hours for admission and examination of patients set out by a general act of the institution; and
5) does not abide by the general acts of the institution concerning the storing of medicaments and medical equipment for which he/she is directly responsible.

(2) The fine referred to in paragraph (1) of this Article shall be charged on the spot of the misdemeanor by the inspector.

Article 314

The revenues of the imposed misdemeanors on the legal entities and natural persons referred to in Articles 305 to 313 of this Law shall be revenues of the Budget of the Republic of Macedonia.

Article 315

(1) The misdemeanor procedure for the misdemeanors envisaged by this Law shall be conducted by the competent court.

(2) Prior to filing a motion for initiation of a misdemeanor procedure, a settlement procedure shall be conducted before the competent court in accordance with the Law on Misdemeanors.

XVIII. TRANSITIONAL AND FINAL PROVISIONS

Article 316

(1) The Government shall establish the network of healthcare institutions within a period of six months as of the day of entry into force of this Law.

(2) The existing healthcare institutions that have concluded an agreement with the Fund before the day of entry into force of this Law shall compose the network of healthcare institutions and shall continue, within the network, to perform the healthcare activity for which they hold a license for work issued in line with the Law on Health Protection ("Official Gazette of the Republic of Macedonia" nos. 38/91, 46/93, 55/95, 10/2004, 84/2005, 111/2005, 65/2006, 5/2007, 77/2008, 67/2009, 88/10, 44/11 and 53/11).
(3) The network of healthcare institutions shall also include all the private healthcare institutions in the primary health protection where the chosen doctors work that require to be in the network of healthcare institutions pursuant to this Law.

(4) The network of healthcare institutions shall also include the existing private healthcare institutions founded on the basis of a lease of premises and equipment of parts of the public healthcare institutions in accordance with the Law on Health Protection ("Official Gazette of the Republic of Macedonia" nos. 38/91, 46/93, 55/95, 10/2004, 84/2005, 111/2005, 65/2006, 5/2007, 77/2008, 67/2009, 88/10, 44/11 and 53/11) which are in abeyance due to election or appointment of the holder of the activity to a public office.

(5) As of the day of establishment of the network of healthcare institutions referred to in paragraph (1) of this Article, licenses for work of healthcare institutions in the network shall be issued for both public and private healthcare institutions that shall perform an activity on the basis of a license, should it be determined by the network.

(6) Until the Government establishes the network, the Fund may conclude agreements only with the chosen doctors.

Article 317

The integrated health information system referred to in Article 28 paragraph (1) of this Law shall be determined within a period of one year as of the day of entry into force of this Law.

Article 318

(1) The existing healthcare institutions shall file an application for renewal of the license for work within a period of one year after the day of establishment of the network of healthcare institutions. The existing healthcare institutions that meet the requirements for renewal of the license for work shall continue to work in the network.

(2) Until the renewal of the license for work referred to in paragraph (1) of this Article, the existing healthcare institutions shall continue to perform the healthcare activity for which they hold a license for work in accordance with the Law on Health Protection ("Official Gazette of the Republic of Macedonia" nos. 38/91, 46/93, 55/95, 10/2004, 84/2005, 111/2005, 65/2006, 5/2007, 77/2008, 67/2009, 88/10, 44/11 and 53/11).

(3) The existing private healthcare institutions, established on the basis of lease of premises and equipment of parts of the public healthcare institutions, in accordance with the Law on Health Protection ("Official Gazette of the Republic of Macedonia" nos. 38/91, 46/93, 55/95, 10/2004, 84/2005, 111/2005, 65/2006, 5/2007, 77/2008, 67/2009, 88/10, 44/11 and 53/11) that cease to operate as of the day the healthcare worker being leased the premises and equipment fulfills the conditions for exercising the age pension, that is, upon his/her personal request, until turning 65 years of age, and the healthcare workers with a high school, two-year post secondary school and higher vocational degree, employed in those institutions and who do not meet the requirements for exercising the age pension shall be taken over by the following license holder for three years.

(4) The non-fulfillment of the obligation for taking over and employment of the healthcare workers referred to in paragraph (3) of this Article by the new license holder shall be considered grounds for cancellation of the license agreement.

Article 319

(1) The minister of health shall, within a period of one year as of the day of entry into force of this Law, adopt the regulations the adoption of which is determined by this Law.
(2) The regulations in force before the day of entry into force of this Law shall apply until the adoption of the regulations of this Law.

**Article 320**

(1) The existing public healthcare institutions shall harmonize their work with the provisions of this Law within a period of three months as of the day of entry into force of this Law.

(2) The public healthcare institutions shall harmonize the statutes with the provisions of this Law within a period of six months as of the day of entry into force this Law.

**Article 321**

(1) The directors of the existing public healthcare institutions appointed upon an announcement until the day of entry into force of this Law shall continue to perform the duty of a director until the expiry of the term of office they have been appointed for.

(2) The members of the governing boards in the existing public healthcare institutions appointed until the day of entry into force this Law shall continue to be members in the governing boards until the expiry of the term of office they have been appointed for.

**Article 322**

The existing collective agreements shall be harmonized with this Law within a period of three months as of the day of entry into force of this Law at the latest.

**Article 323**

(1) The Doctors’, Dental, that is, Pharmaceutical Chamber shall harmonize their work with the provisions of this Law within a period of three months as of the day of entry into force of this Law.

(2) The chambers referred to in paragraph (1) of this Article shall, within a period of three months as of the day of entry into force of this Law, adopt the acts the adoption of which has been determined by this Law.

(3) The chambers referred to in paragraph (1) of this Article shall commence to conduct the professional supervision of the work of the healthcare institutions and the healthcare workers as of 1 January 2013.

(4) Until the commencement of the conducting of the professional supervision referred to in paragraph (3) of this Article, the professional supervision of the work of the healthcare institutions and of the healthcare workers shall continue to be conducted by the Ministry of Health in accordance with the provisions on conducting the professional supervision of the Law on Health Protection (“Official Gazette of the Republic of Macedonia” nos. 38/91, 46/93, 55/95, 10/2004, 84/2005, 111/2005, 65/2006, 5/2007, 77/2008, 67/2009, 88/10, 44/11 and 53/11).

**Article 324**

and the regulations adopted thereon until the day of entry into force of this Law shall be completed in accordance with these regulations.

(2) The healthcare workers with a university degree in the field of medicine and dental medicine who have passed the expert exam or have obtained a basic license for work before the day of entry into force of this Law shall be considered to have a license for work in the primary health protection until the expiry of the validity period of the basic license for work.

**Article 325**


**Article 326**


**Article 327**


**Article 328**

(1) As of the day of entry into force of this Law, the existing public healthcare institutions – health stations shall continue to work as public healthcare institutions – medical centers or polyclinics, depending on the requirements they meet.

(2) As of the day of entry into force of this Law, the existing public healthcare institutions – institutes shall continue to operate as public healthcare institutions – specialized hospitals, depending on which illnesses, what age and which gender the institute has been established for.

(3) As of the day of entry into force of this Law, the public healthcare institution – Center for Medical Rehabilitation "Skopje" shall continue to operate as Public Healthcare Institution – Institute for Medical Rehabilitation "Skopje".

(4) The public healthcare institution – University Clinic for Radiology and the Public Healthcare Institution – University Clinic for Biochemistry shall continue to operate as Public Healthcare
(5) The provision of Article 85 paragraph (3) of this Law, in terms of the requirement for at least five employed doctors of medical science, that is, dental science in the university clinic, shall apply as of 1 January 2016, and by 31 December 2013 it shall be necessary to have at least two employed doctors of medical science, that is, of dental science, by 31 December 2014 it shall be necessary to have at least three employed doctors of medical science, that is, of dental science, and by 31 December 2015 is shall be necessary to have at least four employed doctors of medical science, that is, of dental science.

**Article 329**

The existing healthcare institutions that perform some of the activities referred to in Article 29 paragraph (1) of this Law for which they have a license for work in accordance with the Law on Health Protection ("Official Gazette of the Republic of Macedonia" nos. 38/91, 46/93, 55/95, 10/2004, 84/2005, 111/2005, 65/2006, 5/2007, 77/2008, 67/2009, 88/10, 44/11 and 53/11) shall continue to perform them until the day of establishment of the network of healthcare institutions.

**Article 330**

(1) The Agency shall commence its operation as of 1 January 2013, and until the commencement of operation of the Agency, the Ministry of Health shall carry out the activities within the competence of the Agency.

(2) The reports of the healthcare institutions referred to in Article 238 of this Law shall be submitted to the Ministry of Health until the day of commencement of operation of the Agency.

(3) The acts on internal organization and systematization of the jobs in the Agency shall be adopted within a period of three months as of the day of appointment of the director.

(4) As of the day of commencement of work of the Agency, the employees from the Ministry of Health who perform the activities in the field of accreditation shall be taken over by the Agency.

(5) The equipment, the documents and the other means of work of the Ministry of Health which are related to the performance of the activities by the employees referred to in paragraph (5) of this Article shall be taken over by the Agency.

**Article 331**

The minister of health shall form the Health Council, the Ethical Commission and the coordinating body referred to in Article 248 of this Law within a period of six months as of the day of entry into force of this Law.

**Article 332**

(1) The provisions referred to in Article 142 of this Law shall start to apply as of 1 January 2018.

(2) Until the commencement of application of the provisions of Article 142 of this Law, the implementation of the plan and the program for specializations and subspecializations by the healthcare workers with a university degree, that is, healthcare co-workers with a university degree (hereinafter: the residents) shall be organized and monitored by an authorized healthcare worker, that is, healthcare co-worker (hereinafter: the co-mentor), who meets the criteria concerning the education and experience in the corresponding field of specialization, that is, subspecialization, and an
authorized healthcare worker, that is, healthcare co-worker (hereinafter: the mentor) who meets the criteria concerning the education and experience in the corresponding field of specialization, that is, subspecialization shall coordinate the work of at least three co-mentors and shall monitor the work of the residents guided by the co-mentors he/she coordinates.

(3) During the implementation of the plan and the program for specializations and subspecializations, the co-mentor shall also ensure additional activities and shall be responsible, in cooperation with the authorized healthcare worker, that is, healthcare co-worker referred to in Article 144 of this Law, to make possible for the resident to acquire the skills under the plan and the program for specializations, that is, subspecializations and the resident to succeed in mastering the knowledge and skills during the course of specialization, that is, subspecialization.

(4) The co-mentor shall have the role of a guide to the resident in the course of the specialization, that is, subspecialization and may guide three residents, that is, six residents in the family medicine specialization at the most.

(5) The co-mentor referred to in paragraph (4) of this Article may guide three more residents, that is, six more residents specializing in family medicine at the most, from among the healthcare workers, that is, healthcare co-workers, employed in private healthcare institutions, that is, other legal entities and from among the unemployed.

(6) If the co-mentor does not make possible for the resident to acquire the skills under the specialization, that is, subspecialization plan and program, he/she cannot guide a new resident.

(7) If at least two residents of one co-mentor have not successfully acquired the particular skills under the specializations, that is, subspecializations plan and program within a period of five years, the co-mentor shall be revoked the authorization for carrying out co-mentor activities.

(8) The healthcare workers and the healthcare co-workers referred to in paragraph (2) of this Article shall be authorized by the minister of health, upon a proposal of the faculty of medicine, dental medicine, that is, pharmacy, to be mentors, that is, co-mentors.

(9) The detailed criteria referred to in paragraph (2) of this Article shall be prescribed by the minister of health.

**Article 333**


**Article 334**

This Law shall enter into force on the eight day as of the day of its publication in the “Official Gazette of the Republic of Macedonia”.

<table>
<thead>
<tr>
<th>PROVISIONS</th>
<th>OF OTHER LAWS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article</td>
<td>13</td>
</tr>
<tr>
<td>The license granting procedures commenced in accordance with the Law on Health Protection (&quot;Official Gazette of the Republic of Macedonia” no. 43/2012) and the regulations adopted thereto, shall be completed in accordance with those regulations.</td>
<td></td>
</tr>
</tbody>
</table>
The concessions awarded in accordance with the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 43/2012) and the regulations adopted thereto shall be considered as licenses in accordance with this Law, with a validity period in accordance with the regulations in accordance with which they have been issued.

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 87/2013):

**Article 20**
The provisions of Articles 1 and 14 of this Law shall start to apply as of the 13 July 2013.

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 164/2013):

**Article 4**
This Law shall enter into force on the eight day as of the day of its publication in the "Official Gazette of the Republic of Macedonia" and the provision of Article 3 of this Law shall start to apply as of 1 May 2014.


**Article 22**
The existing public healthcare institutions shall harmonize their internal organization with Article 91 paragraph (2) of this Law until 1 September 2014 at the latest.

**Article 24**
The minister of health shall adopt the bylaw referred to in Article 164-c paragraph (6) of this Law within a period of three months as of the day of entry into force of this Law.

**Article 26**
The persons who have passed the director examination in accordance with the provisions of the Law on Health Protection ("Official Gazette of the Republic of Macedonia" nos. 43/2012, 145/2012, 87/2013 and 164/2013) shall be recognized the passed director examination.


**Article 21**
Article 7 which prescribes that a head of a unit, in accordance with Article 91-a paragraph (2) line 6 of this Law, may be a person who stayed abroad for at least five years in total in the last six years for the purpose of professional development or for the purpose of participation in international scientific events as a lecturer or educator, shall start to apply as of 1 June 2015.

Article 7 which prescribes that a head of a unit, in accordance with Article 91-a paragraph (2) lines 4 and 5 of this Law, may be a person who have published at least one paper in a scientific journal having an impact factor or who has been a holder or coordinator of a national, regional or international scientific and research project and who have introduced at least two new healthcare methods or procedures in at least two public healthcare institutions (in a public healthcare institution at tertiary level, in a clinic and/or a general hospital) shall start to apply as of 1 January 2015.

**Article 23**
The provision of Article 164 paragraph (2) of the Law on Health Protection ("Official Gazette of the Republic of Macedonia" nos. 43/2012, 145/2012, 87/2013 and 164/13) shall apply until 31
Article 25
Article 9 which prescribes the manner of taking the director examination shall start to apply one year as of the day of entry into force of this Law. The Ministry of Health shall implement the single electronic system for the director examination until the day of beginning of application of Article 9 of this Law at the latest.

Article 29
The provisions of Part 3-a. External control of the quality of laboratory services shall start to apply as of 1 June 2014.

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia” no. 43/2014):

Article 7
The directors of the public healthcare institutions who have been appointed before the beginning of application of Articles 2 and 3 of this Law, shall continue to exercise the office until the expiry of the term of office for which they have been appointed.

Article 8
The procedures related to the healthcare workers and the healthcare co-workers, as well as the procedures related to the employees in the public healthcare institutions who are not healthcare workers and healthcare co-workers, referring to employment, disciplinary procedures, material liability and the procedures for assessment of the persons initiated before the beginning of application of this Law, shall end in accordance with the Law on Health Protection ("Official Gazette of the Republic of Macedonia" nos. 43/2012, 145/2012, 87/2013 and 164/2013).

Article 9
The employees who, on the day of entry into force of this Law, work at a position of category A - healthcare workers with a higher education in the field of medicine, dentistry and pharmacy, at a position of category B - healthcare workers with a higher vocational education in the field of medicine and dentistry, and at a position of category E - healthcare co-workers of level E1 to level E6, who are to be entitled to a pension within the following period of ten years as of the beginning of application of this Law, should not submit a proof for knowledge of a foreign language, appropriate to their position.

Article 10
The employees who, on the day of entry into force of this Law, work at a position of category B - healthcare workers with a higher vocational education in the field of medicine and dentistry, and have a secondary or a two-year post-secondary education in the field of medicine or dentistry, shall continue to carry out the duties under this position until the fulfillment of the requirements for the degree of professional training necessary for that position, but not longer than five years as of the day of entry into force of this Law. The employee referred to in paragraph (1) of this Article who does not submit proofs for the fulfillment of the requirements for the degree of professional training necessary for the position of category B - healthcare workers with a higher vocational education in the field of medicine and dentistry, shall be reassigned to a position appropriate to his/her degree of professional training by a decision of the management body of the public healthcare institution. The employee referred to in paragraph (1) of this Article who submits proofs for the fulfillment of the requirements for the degree of professional training necessary for the position of category B - healthcare workers with a higher vocational education in the field of medicine and dentistry, shall be reassigned to the same position or to a position appropriate to his/her degree of professional training by a decision of the management body of the public healthcare institution, and the complete work experience gained in the public healthcare institution as a healthcare worker shall be considered as his/her work experience in the profession. Paragraph (1) of this Article shall not apply to the employees who, on the day of entry into force of this Law, work at a position of category B - healthcare workers with a higher vocational education in the field of medicine and dentistry and who are to be entitled to a pension within the following period of ten years as of the beginning of application of this Law.

Article 11
The employees who, on the day of entry into force of this Law, work at a position of category
D - healthcare workers with a secondary vocational education in the field of medicine, dentistry and pharmacy, levels D4 and D5, and have completed a primary education or have not completed a secondary education in the field of medicine or have inadequate secondary education, shall continue to carry out the duties under this position until the fulfillment of the requirements for the degree of professional training necessary for that position, but not longer than five years as of the day of entry into force of this Law.

The law amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 43/2014): Article 12

An employee who has been employed in a public healthcare institution as to the day of beginning of application of this Law should submit proofs for knowledge of foreign languages and knowledge of office computer programs, appropriate to the category and levels of his/her position, to the management body of the public healthcare institution within a period of two years as of the day of beginning of application of this Law.

The employee referred to in paragraph (1) of this Article who does not submit proofs for knowledge of foreign languages and knowledge of office computer programs in accordance with paragraph (1) of this Article shall be reassigned to a one level lower position that the position he/she has worked at on the day of entry into force of this Law by a decision of the management body of the public healthcare institution, except the employees who have been assigned to a position of entry level on the day of beginning of application of this Law and whose salary shall be lowered by 10%.

The employee referred to in paragraph (1) of this Article whose salary has been lowered by 10% in accordance with paragraph (2) of this Article, may submit proofs for knowledge of foreign languages and knowledge of office computer programs to the managerial person in the institution at any time, upon which the management body of the public healthcare institution shall adopt a decision based on which the decision on lowering the salary ceases to be valid. Paragraphs (1) and (2) of this Article shall not apply to the employees who are to be entitled to a pension within the following period of ten years as of the beginning of application of this Law.

The State Administrative Inspectorate, within a period of three months as of the expiry of the deadline referred to in paragraph (1) of this Article, shall make an inspection of the implementation of paragraphs (1) and (2) of this Article in all public healthcare institutions.


The provisions of Articles 2, 3 and 4 of this Law shall start to apply one year as of the day of entry into force of this Law, except the provisions referring to the requirement for knowledge of a foreign language which shall start to apply two years as of the day of entry into force of this Law.

Article 14
The provisions of Articles 1, 5 and 6 of this Law shall start to apply as of the beginning of application of the Law on Administrative Servants ("Official Gazette of the Republic of Macedonia" no. 27/2014) and the Law on Public Sector Employees ("Official Gazette of the Republic of Macedonia" no. 27/2014).