

# Law on Health Protection

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## I. GENERAL PROVISIONS

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### Subject of regulation

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#### 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

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#### 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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

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## 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

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### 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

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### 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

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### 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

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### Article 14

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

## Definitions of the terms

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### 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 his/her 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 medications 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 the 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 the 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 the 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 successfulness 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. "Optometrist" is a healthcare worker who holds a university degree in the field of optometry and ocular optics, who has completed the probationary work (at least 15 years of work experience after the graduation as optician in ocular optics in production and/or sale of optic equipment and devices or at least two years of work experience in the performance of the healthcare activity of optometry under the supervision of a doctor of medicine specialist in ophthalmology) and has passed the professional examination, who carries out a healthcare activity of optometry in accordance with this Law and who may work in a public healthcare institution, in a private specialist ophthalmology healthcare institution, in a shop specialized for retail sale of medical devices entered in the register of shops specialized for medical devices, and in a legal entity – trade company doing a business in ocular optics.
37. "Pharmacists" is a person holding a bachelor's or master's degree in pharmacy;
38. "Pharmaceutical activity" is a part of the healthcare activity that includes uninterrupted, continuous supply of medications 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 medications and medical devices, and monitoring of the effects of the use of medications;
39. "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;
40. "Internal quality control" is a systematic control of professional activities in the healthcare institutions with regard to the prescribed standards; and
41. "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

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

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### 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 medications 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, 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/liter pure alcohol, as well as from part of the cigarette excise in the amount of 0,053 Denars per piece (cigarette), intended for procurement of medications for rare diseases.

(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 at the time of collecting the beer, the ethyl alcohol and the cigarette excise and it shall pay it at a corresponding account of the Ministry of Health within the treasury account.

## Network of healthcare institutions

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### 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, and
- 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

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### 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

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### 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

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### 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

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### 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 professional, organizational and technologically complex and multidisciplinary healthcare treatment laid down in Article 17 paragraph (1) of this Law.

## Network of emergency medical care

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### 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

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### 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 professional 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

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### 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 professional 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

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### 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

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### Contents of the healthcare activity

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#### 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,
- health and obstetrics care,
- emergency medical care,
- life-saving transports,
- palliative care,
- examination of deceased persons,
- pathoanatomical activity,
- forensic medicine,
- supply of blood and blood components,
- procedures for harvesting and storing gametes,
- biomedical assisted fertilization 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,
- production of radiopharmaceutical preparations,
- detection and correction of refractive anomalies with eye-glasses and contact lenses and, in relation to such detection, replacement and prescription of eye-glasses and/or detection, replacement or prescription of contact lenses, with the exception of children of up to 14 years of age, in healthcare institutions and legal entities under professional supervision of a commission formed by the minister of health in cooperation with the professional association of doctors of medicine specialists in ophthalmology.



- diagnostics of metabolic dysfunction by using positron emission tomography, 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.

(4) The standards for medical devices implanted during particular health services in view of the material which they should be made from, depending on the indication, age and health condition of the patient, shall be determined by the minister of health for which he/she shall form an expert commission in which experts in that field shall also be members.

Instructions for evidence-based medicine, protocols for carrying out the healthcare activity in the healthcare institutions from organizational point of view and a rulebook for hospital culture

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#### 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 point of view shall be mandatorily performed in accordance with the protocols determined by the minister of health.

(5) The way the healthcare workers and healthcare co-workers, as well as any other person employed and person engaged on any other ground in the healthcare institution, behave and act at work by introducing principles and rules of conduct and operation, according to which these persons act in the execution of the work in order to ensure application of, and compliance with, the principles of legality, professional integrity, efficiency, effectiveness and dedication in the performance of their official duties, shall be determined by the minister of health by a rulebook for hospital culture.

(6) Upon the adoption of the professional instructions referred to in paragraph (1) of this Article, the protocols referred to in paragraph (4) of this Article and the rulebook for hospital culture referred to in paragraph (5) of this Article, the Ministry of Health shall be obliged to immediately publish them on the website of the Ministry and in the "Official Gazette of the Republic of Macedonia".

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

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

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#### 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 the 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.

(4) The Ministry of Health shall, by a travel order, assign a healthcare worker, that is, a healthcare co-worker employed in a public healthcare institution in the network, not longer than three working days during one month, to work in another public healthcare institution in the network, provided that the existing number of employed healthcare workers and/or healthcare co-workers in particular public healthcare institutions or at the level of municipalities, at the level of regions or at the level of the Republic of Macedonia within the network at the primary health protection and/or in the network at the level of secondary

and tertiary health protection for carrying out a specialist and consultative, diagnostic health activity and hospital activity does not make the achievement of the principle of accessibility and the principle of continuity possible.

(5) The Ministry of Health shall, by a consent of the healthcare worker, that is, the healthcare co-worker given in a written form, by a travel order, assign a healthcare worker, that is, a healthcare co-worker employed in a public healthcare institution in the network, not longer than five working days during one month, to work in another public healthcare institution in the network in the cases referred to in paragraph (4) of this Article.

(6) The healthcare institution in the network where the healthcare worker, that is, the healthcare co-worker is assigned to work by a travel order referred to in paragraph (4) of this Article, shall pay him/her travel and daily costs for the period he/she is assigned for in accordance with the law and the collective agreement.

(7) The director of the healthcare institution where the healthcare worker, that is, the healthcare co-worker referred to in paragraph (4) of this Article is employed shall be obliged, within a period of five days as of the day he/she has failed to report to work, that is, failed to execute the duties in the other healthcare institution, to initiate a procedure for establishment of a disciplinary liability of the healthcare worker, that is, the healthcare co-worker referred to in paragraphs (4) and (5) of this Article.

(8) Immediately upon the issuance of the travel order referred to in paragraph (4) and (5) of this Article, and in order for the Health Insurance Fund of Macedonia to issue an approval for the healthcare worker, that is, the healthcare co-worker to use the seal in the course of rendering healthcare services in the public healthcare institution where he/she is assigned to work, the Ministry of Health shall inform the Health Insurance Fund of Macedonia which healthcare worker, that is, the healthcare co-worker is assigned to work by a travel order.

## Healthcare activity and parts of the healthcare activity performed solely within the network

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### 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 fertilization 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 health condition 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

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### 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 medications; 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 medications and medical devices.

## Entities that carry out healthcare activity at primary level

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### 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

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#### 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 professional 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 medications 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 deterioration,
- 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.

(4) 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 has 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

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### 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

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### 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

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### 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

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### 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

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### Article 37

The healthcare activity at tertiary level shall include:

- provision of health services that require professional, 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,
- transfer of knowledge and skills to the healthcare institutions at secondary and primary level,
- 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 professional 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

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### 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

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### Article 39

(1) The schedule for using specialist, consultative, and hospital health services, as well as the schedule for performing surgical interventions 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 in an integrated health information system 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.

(7) The data on the patient's health insurance contained in the electronic list of scheduled examinations and interventions, and especially on the validity of the patient's health insurance on the day when the examination, that is, the intervention scheduled through the electronic list of scheduled examinations and interventions should be performed, shall be taken from the Health Insurance Fund of Macedonia every working day, at least three hours before the start of the working hours in the public healthcare institution."

(8) The Ministry of Health shall take the data on the temporary inability to work due to illness and injury of the patient, contained in the integrated health information system, from the chosen doctors every day.

(9) Based on the data referred to in paragraph (8) of this Article, on a request of the employer, the Ministry of Health shall issue:

- a certificate containing data on the period during which the chosen doctor has determined that the patient who is a full time employee at the employer who submits the request is temporary unable to work due to his/her illness or injury, within a period not longer than five days as of the day of submission of the request by the employer and
- a certificate containing data on the day when the period during which the chosen doctor has determined that the patient who is a full time employee at the employer who submits the request is temporary unable to work due to his/her illness or injury begins, within a period not longer than 24 hours as of the day of submission of the request by the employer.

(10) The data on the period in the certificate referred to in paragraph (9) line 1 of this Article shall be determined by stating the day when the period starts and the day when the period ends, and in the certificate referred to in paragraph (9) line 2 of this Article by stating the day when the period starts. The Ministry of Health, except these data, shall not give any other personal and medical data on the patient, and the employer shall be obliged to keep the received data in accordance with the regulations on keeping a professional and business secret, as well as on personal data protection.

## Referral of patients

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### 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 at secondary and tertiary level of health protection shall be obliged to determine in advance a calendar of activities not earlier than the tenth day of the current month for the following month for each healthcare worker who renders specialist and consultative services in the healthcare institution (hereinafter: the calendar of activities) and a calendar of available appointments for using the medical equipment which the healthcare institution uses for rendering specialist and consultative services.

(3) The calendar of activities referred to in paragraph (2) of this Article shall include a time schedule for all activities that the healthcare worker who renders specialist and consultative services carries out during the working hours, and especially for:

- holding the meeting of the professional collegium,
- carrying out examinations in a specialist and consultative clinic,
- rendering specialist and consultative services by using medical equipment,
- carrying out control examinations,
- rendering services related to carrying out a hospital health activity,
- carrying out surgical interventions,
- carrying out consilium examination,
- on-duty work, and
- participation in lectures.

(4) For the purpose of providing the calendar referred to in paragraph (2) of this Article, the healthcare workers who provide services in the healthcare institutions in the network at secondary and tertiary level of health protection shall be obliged to determine in advance a calendar of activities not earlier than the fifth day of the current month for the following month and to submit it to the director of the healthcare institution.

(5) The healthcare worker who renders specialist and consultative services in the healthcare institutions in the network at secondary and tertiary level of health protection shall be obliged to refer the patients who he/she has examined, that is, who he/she has made an intervention on at secondary and tertiary level of health protection to additional specialist and consultative services through the electronic list of scheduled examinations and interventions for the purpose of diagnosing and treating the diseases and the injuries and rehabilitating, for which he/she shall issue an interspecialist referral, a specialist and sub-specialist referral, a referral for radio diagnostics and a referral for laboratory services.

(6) The healthcare worker who renders specialist and consultative services in the healthcare institutions in the network at secondary and tertiary level of health protection shall be obliged to refer the patients who he/she has examined, that is, who he/she has made an intervention on to a control specialist and consultative service through the electronic list of scheduled examinations and interventions for which he/she shall issue a control referral.

(7) The healthcare worker who renders specialist and consultative services in the healthcare institutions in the network at secondary and tertiary level of health protection shall be obliged to refer the patients who he/she has examined, that is, who he/she has made an intervention on at secondary and tertiary level of health protection to a hospital treatment in the institution where he/she works or to a surgical intervention which he/she is making, for which he/she shall issue a hospital referral and/or hospital referral for surgical interventions.

(8) The duration of the examinations in the specialist and consultative clinics and of the provision of specialist and consultative services by using medical equipment, determined based on the type of specialty of the healthcare worker who renders the specialist and consultative service, the type of medical equipment, as well as the level of healthcare activity carried out in the healthcare institution, shall be determined by the minister of health, upon a received opinion of the Doctors' Chamber, that is, Dental Chamber.

(9) The healthcare worker who performs surgical interventions in the healthcare institutions in the network at secondary and tertiary level of health protection shall be obliged to schedule appointments for elective surgical intervention in the calendar of activities referred to in paragraph (2) of this Article.

(10) Based on the appointments for elective surgical interventions referred to in paragraph (9) of this Article and the issued hospital referrals for surgeries referred to in paragraph (7) of this Article, a list containing a time schedule of patients who should undergo a surgical intervention (hereinafter: the surgery program) shall be included in the lists of scheduled examinations and interventions. The surgery program shall be approved by the professional collegium of the healthcare institution where the surgical intervention is performed in the current week for the next week. Every change in the surgery program shall be mandatorily entered in the electronic list of scheduled examinations and interventions by stating the reasons due to which the change is made and the healthcare institution shall be obliged to notify the patients thereof immediately, and within a period of 24 hours at the latest as of the occurrence of the change.

(11) 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.

(12) The patients shall be obliged to observe the appointment scheduled via the electronic list of scheduled examinations and interventions and to cancel the examination, that is, the intervention at least 24 hours before the scheduled appointment if they are prevented to come or the need of a specialist and consultative service for which the appointment is scheduled has ceased. The public healthcare institution may demand from the patient who has cancelled the examination, that is, the intervention more than twice during one month,

that is, four times or more during one year without observing the cancellation deadline, as well as from the patient who has not cancelled the examination, that is, the intervention not even once during the month, that is, during one year, at the first following use of the same health service, to participate with personal funds in the amount of 50% in the total costs for the health service. In this case, the patient shall participate with personal funds in increased amount only for the first following use of the same health service.

(13) If the patient is late for the appointment 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 appointments at the end of the working day.

(14) If the patient fails to come to the appointment scheduled via the electronic list of scheduled examinations and interventions on the day it is scheduled, he/she should reschedule the appointment via his/her selected doctor.

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

(16) The director of the healthcare institution shall reimburse the travel costs referred to in paragraph (15) of this Article within a day as of the submission of the request of the patient referred to in paragraph (15) 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 appointment has not been kept or due to whom the patient has not been informed within the time period referred to in paragraph (15) of this Article to reimburse the costs referred to in paragraph (15) of this Article.

(17) The director of the public healthcare institution shall be obliged to ensure that each patient is informed about his/her right referred to in paragraph (15) of this Article by a written notification displayed at the entrance of the healthcare institution, in an easily visible and accessible place, printed on a plasticated paper with dimensions 100 cm x 50 cm and framed.

(18) For the purpose of unobstructed functioning of the electronic list of scheduled examinations and interventions, the directors of the healthcare institutions in the network at 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.

(19) 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.

(20) The directors of the healthcare institutions in the network at 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 (18) and (19) 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.

(21) 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 (18), (19) and (20) of this Article.

(22) Upon the adoption of the bylaw referred to in paragraph (8) of this Article, the Ministry of Health shall be obliged to immediately publish it on the website of the Ministry and in the "Official Gazette of the Republic of Macedonia".

## Observance of the appointment scheduled through the electronic list of scheduled examinations and interventions by the healthcare worker who renders specialist and consultative services

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### Article 39-b

(1) The healthcare worker who renders specialist and consultative services shall be obliged to observe the appointment scheduled through the electronic list of scheduled examinations and interventions.

(2) The healthcare worker who renders specialist and consultative services shall have the right to postpone the start of the scheduled examination, that is, intervention for 15 minutes at the most as from the appointment scheduled through the electronic list of scheduled examinations and interventions, and shall have the right to postpone it for more than 15 minutes if there are objective and justifiable reasons thereof.

(3) Objective and justifiable reasons referred to in paragraph (2) of this Article shall be the reasons related to rendering health services by the healthcare worker who renders specialist and consultative services to another patient, that is, other patients, and especially for providing emergency health services the failure of which to be performed in a short period of time could cause irreparable and severe damage to the health of the patient or

his/her death or due to replacement of an absent healthcare worker and/or reasons related to carrying out the healthcare activity of the public healthcare institution and/or postponement of the start of the scheduled appointment, that is, intervention due to interruptions in the internet connection or in the distribution of electricity and water, and similar reasons related to the operation of the healthcare worker in the healthcare institution.

(4) The patient who is not going to be examined at the time of the scheduled appointment or who is going to be examined with a delay which is not in compliance with paragraphs (2) and (3) of this Article, shall submit a notification in a written form or orally on minutes to the head of the internal organizational unit in the public healthcare institution and/or to the management body in the healthcare institution, informing that the examination is not made at the time of the appointment scheduled through the electronic list of scheduled examinations and interventions or that the examination, that is, the intervention has started with a delay which is not in compliance with paragraphs (2) and (3) of this Article.

(5) The patient shall submit the notification in a written form, that is, he/she shall give it orally the same day, and the following day at the latest as of the day when the examination has not been made at the time of the appointment scheduled through the electronic list of scheduled examinations and interventions, that is, when the examination, that is, the intervention has started with a delay.

(6) The management body of the healthcare institution shall organize the printing of the notification in a written form in sufficient number of copies and shall place them at the entrance of the healthcare institution, in an easily visible and accessible place.

(7) The patient shall submit the notification in a written form in at least two copies, one of which he/she shall keep after the receipt and the confirmation of the receipt of the notification in accordance with the regulations on office and archive operation. In the case where the notification is given orally on minutes, one original copy of the minutes shall be given to the patient who has given the notification orally.

(8) A disciplinary procedure shall be initiated against the healthcare worker who renders specialist and consultative services and who has not made the examination at the time of the appointment scheduled through the electronic list of scheduled examinations and intervention or has started the examination, that is, the intervention with a delay without having objective and justifiable reasons in accordance with paragraph (3) of this Article based on the notification submitted by the patient in accordance with paragraph (4) of this Article to the head of the internal organizational unit of the public healthcare institution and/or to the management body of the healthcare institution, that is, based on the minutes referred to in paragraph (4) of this Article in the case where the notification is given orally. If the notification is submitted, that is, is given orally on minutes to the head of the internal organizational unit of the public healthcare institution, he/she shall be obliged to forward

the notification to the management body of the healthcare institution immediately upon its receipt, and within a period of one hour as of the hour he/she has received the notification at the latest, that is, during the first hour of the next working day at the latest.

(9) The management body of the healthcare institution shall establish a commission for conducting the disciplinary procedure for the disciplinary offense referred to in paragraph (8) of this Article within a period of three days as of the day when the patient has submitted the notification referred to in paragraph (4) of this Article in a written form, that is, has given it orally on minutes to the head of the internal organizational unit of the public healthcare institution, that is, to the management body of the healthcare institution. The management body of the healthcare institution shall notify the patient that the commission is established within a period of three days as of the day of establishment of the commission.

(10) The management body of the healthcare institution shall, within a period of 15 days as of the day of initiation of the procedure, based on a proposal of the commission referred to in paragraph (9) of this Article, adopt a decision imposing a disciplinary measure for the disciplinary offense. The management body of the healthcare institution shall submit a copy of the decision imposing the disciplinary measure for the disciplinary offense to the patient who has submitted, that is, has given the notification within a period of three days as of the day of adoption of the decision.

(11) If the patient does not receive a notification on establishment of a commission for conducting a disciplinary procedure for a disciplinary offense, that is, does not receive a decision imposing a disciplinary measure for a disciplinary offense within the deadlines set in paragraphs (9) and (10) of this Article, it shall be deemed that a commission for conducting a disciplinary procedure for a disciplinary offense is not established, that is, a disciplinary measure for a disciplinary offense is not imposed.

(12) The patient referred to in paragraph (4) of this Article shall have the right to submit a complaint to the Ministry of Health if he/she does not receive a notification on establishment of a commission for conducting a disciplinary procedure for a disciplinary offense, that is, does not receive a decision imposing a disciplinary measure for a disciplinary offense within the deadlines set in paragraphs (9) and (10) of this Article. The patient shall attach a copy of the notification in a written form, that is, a copy of the minutes in the case where the notification is given orally on minutes to the complaint.

(13) In the case referred to in paragraph (12) of this Article, the minister of health shall determine a contractual penalty in accordance with Article 104 paragraph (4) of this Law for the management body of the public healthcare institution.

(14) If, due to dealing with an emergency case, temporary prevention to work due to illness and injury of the healthcare worker, failure of the medical equipment, interruption in the distribution of electricity, interruption in the internet connection, and/or reduction of the



availability of the internet connection which leads to instability or inaccessibility of the electronic system of scheduled examinations and intervention, it is obvious that the conditions to make the examinations in accordance with the electronic list of scheduled examinations and interventions are not met, the director shall be obliged, by a written notification printed on a plasticated paper with dimensions 100 cm x 50 cm, placed in a visible place in the waiting room of the public healthcare institution, to inform that, due to justifiable reasons, it is not possible to wholly respect the appointment scheduled through the electronic list of scheduled examinations and interventions that day. In addition to the notification for the patients in a written form by placing a written notification, the director shall be obliged to also ensure that the patients found in the waiting room are informed orally by designating an employee of the public healthcare institution who shall be obliged to constantly be present in the waiting room and to tell and explain to all the patients found in the waiting room and to the patients who are to come at the scheduled appointment, in a personal and direct communication, the reasons why the examination, that is, the intervention is not possible to be made in the scheduled time, as well as to make a new appointment through the electronic list of scheduled examinations and interventions if the examination, that is, the intervention has not been made.

(15) If no person has been present in accordance with paragraph (14) of this Article, if he/she has not been informed and explained, in a personal and direct communication, the reasons why the examination, that is, the intervention has not been possible to be made in the scheduled time, and if the examination, that is, the intervention has not been made, but a new appointment through the electronic list of scheduled examinations and interventions has not been made, the patient shall submit a notification in a written form or orally on minutes to the head of the internal organizational unit in the public healthcare institution and/or to the management body of the healthcare institution. The patient shall give the notification in a written form or orally on minutes within the deadline referred to in paragraph (5) of this Article, and the provisions of paragraphs (6) through (13) of this Article shall also apply to this case.

(16) In the case referred to in paragraph (14) of this Article, the director shall be obliged to send a notification through the integrated health information system established in accordance with the regulations on records in the field of health of the reasons why the examination, that is, the intervention has not been made in the time scheduled through the electronic list of scheduled examinations and interventions, that is, of the reasons why the examination, that is, the intervention has started with a delay, and the time period when such reasons existed, of the new appointments scheduled because the examinations have not been made in the time scheduled through the electronic list of scheduled examinations and interventions, as well as a notification of the name and surname of the person employed in the public healthcare institution referred to in paragraph (14) of this Article who has been obliged to inform the patients orally about the reasons why the examination, that is, the intervention has not been possible to be made in the scheduled time.

(17) The form and the contents of the notification in a written form referred to in paragraphs (4) and (15) of this Article shall be determined by the minister of health.

## Control of the referral of patients and of the electronic list of scheduled examinations and interventions for using health services

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### Article 39-c

(1) The Ministry of Health shall control the electronic list of scheduled examinations and interventions, especially with regard to:

- 1) the contents of the data kept in the electronic list of scheduled examinations and interventions and the manner of its keeping,
- 2) the deadlines for determination of the calendar of activities and the calendar of available appointments for specialist and consultative services by the medical director of the healthcare institution, that is, the healthcare workers who render specialist and consultative services in the healthcare institution,
- 3) the number of determined free periods during the month,
- 4) the observance of the time of the appointment scheduled through the electronic list of scheduled examinations and interventions by the patients and by the healthcare workers who render specialist and consultative services in the healthcare institution,
- 5) the reimbursement of the travel costs incurred by the patient due to scheduled appointment failure for whatever reason related to the healthcare institution,
- 6) the provision of permanent internet connection with availability of 99,9%, that is, backup permanent connection via symmetrical connection, that is, asymmetrical connection which shall be used solely for communication with the Ministry of Health and the Fund to the healthcare institutions in the network at secondary and tertiary level of health protection and to the healthcare institution where the chosen doctors work, with regard to the service-level agreements concluded with the operators that provide internet connection to these healthcare institutions,
- 7) whether the healthcare worker who renders specialist and consultative services has designated appointments for carrying out elective surgical interventions;
- 8) whether the surgery program with a list that contains a time schedule of patients who should undergo an elective surgical intervention is entered in the electronic list of scheduled examinations and interventions, as well as whether the changes in the appointments, if there are any, are entered and whether the patients are informed thereof;
- 9) whether the healthcare worker who renders specialist and consultative services issues an interspecialist referral, a specialist and sub-specialist referral, a referral for radio diagnostics and a referral for laboratory services, a referral for control examinations, a hospital referral and a surgery hospital referral;
- 10) whether the examinations and the interventions scheduled based on a priority referral are made in a period when there are no appointments for examinations and interventions scheduled through the electronic list of examinations and interventions, and
- 11) whether there is a notification in the electronic list of examinations and interventions of

the absence of the healthcare worker who renders specialist and consultative services and/or of the malfunction of the medical equipment due to which the examination, that is, the intervention should be cancelled and rescheduled.

(2) The healthcare institutions shall be obliged to ensure the conducting of the control by the authorized persons of the Ministry of Health, as well as to place the whole medical documentation related to the rendered health services to insured persons for inspection.

## Authorized person in charge of control

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### Article 39-d

(1) The control shall be conducted by a person in charge of control, authorized by the minister of health, employed in the Ministry of Health or a person expert, engaged by the Ministry of Health (hereinafter: the authorized person in charge of control).

(2) The authorized person in charge of control, in the course of conducting the control in the healthcare institutions, shall identify him/herself by an identification card, issued by the minister of health.

(3) The authorized person in charge of control shall be personally liable for his/her work and shall be obliged to keep the data referring to the medical and non-medical documentation as a professional and business secret.

(4) The authorized person in charge of control shall be independent in his/her work, within the prescribed authorization, shall be obliged to act conscientiously and without bias in the performance of his/her work for which he/she shall be accountable to the minister of health.

(5) The authorized person in charge of control shall be held liable if:

- 1) in the course of the control, he/she does not order, by a decision, taking measures and activities which he/she has been obliged to take in accordance with the law;
- 2) he/she exceeds his/her statutory authorizations;
- 3) he/she abuses the official duty;
- 4) he/she does not submit a report, that is, does not notify the competent bodies of the established faults; and
- 5) he/she does not identify him/herself before the beginning of the control.

(6) The procedure for establishment of the disciplinary liability of the authorized person in charge of control shall be conducted in accordance with this Law.

(7) Depending on the size of the control, the control shall be conducted by at least two authorized persons in charge of control.

(8) During the control, the authorized person in charge of control shall be authorized to make an inspection in the electronic list of scheduled examinations and interventions, to ask for statements from the responsible employees, statements from witnesses, and if needed, may use services of other experts.

(9) The form and the contents of the identification card of the authorized persons in charge of control, as well as the manner of issuance and revocation of the identification card for conducting control, shall be determined by the minister of health.

(10) Upon the adoption of the bylaw referred to in paragraph (9) of this Article, the Ministry of Health shall be obliged to immediately publish it on the website of the Ministry of Health and in the "Official Gazette of the Republic of Macedonia".

## Out-of-field, field, regular and extraordinary control

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### Article 39-e

(1) The Ministry of Health shall conduct out-of-field and field control.

(2) The out-of-field control shall be conducted in the Ministry of Health.

(3) The field control shall be conducted in the premises of the entity under control and during the control, the authorized person in charge of control shall have the right to make a direct inspection in the operation of the entity under control.

(4) The out-of-field control shall be conducted based on the regular analysis of the submitted reports by the healthcare institutions; the received reports from the State sanitary and Health Inspectorate and other institutions, and other relevant data and documents on the health system.

(5) The control shall be conducted as regular, extraordinary and repeated.

(6) The regular control shall be conducted according to annual, that is, monthly plans where the controls are planned.

(7) The minister of health shall adopt the work plans referred to in paragraph (6) of this Article until 15 December in the current year for the next year at the latest.

(8) If the authorized person in charge of control does not find the responsible person in the entity under control on the day when the regular control is announced, the authorized person in charge of control shall conduct the control in the presence of an official or other present person.

(9) The extraordinary control shall be conducted on a request of the minister of health or based on an initiative submitted by state bodies, natural persons or legal entities, as well as *ex officio* in the case of suspicion of the authorized person in charge of control.

(10) The extraordinary control may be also conducted based on indications, knowledge and information about irregularities in the work of the healthcare institution and based on complaints of patients.

(11) The repeated control shall be conducted upon the expiry of the deadline set in the minutes of the completed control, and the authorized person in charge of control, during the establishment of the actual situation, shall state that the entity under control has acted, partially acted, or has not acted according to the minutes of the completed control.

(12) The failure to act, that is, the partial acting upon the minutes of the completed control, shall constitute a basis for determination of a contractual penalty for the director, a misdemeanor procedure against the healthcare institution, and a disciplinary procedure against the person employed in the healthcare institution under control and who has committed the irregularity, that is, has not acted, that is, partially acted according to the minutes of the completed control.

## Procedure for conducting control

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### Article 39-f

(1) The procedure for conducting the control shall, by a rule, include preparation, conducting control, establishment of facts, and preparation of minutes, report or notification.

(2) The preparation for control shall include procedures for provision and analysis of data and documentation that are needed for conducting the control.

(3) The control shall be conducted without prior notification by a direct inspection in the work of the entity under control.

(4) The establishment of facts shall be the last part of the control and shall be an integral part of the minutes, the report or the notification.

(5) The control shall cover the period of the current year, and if needed may cover a previous period in accordance with the order for control.

## Minutes of the completed control

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### Article 39-g

- (1) The authorized person in charge of control shall prepare minutes of the completed control at the place of conducting the control. The minutes shall be signed by the authorized person in charge of control and the entity under control and one copy of the minutes shall be given to the entity under control, and if it is not possible the minutes to be prepared during the control due to the size and the complexity of the control and the other circumstances, the minutes shall be composed in the official premises of the Ministry of Health within a period of three days as of the day of conducting the control with an explanation of the reasons why the minutes are prepared in the official premises of the Ministry of Health.
- (2) The minutes shall be signed by the authorized person in charge of control who has conducted the control and a representative of the entity who has been present during the control.
- (3) The authorized person in charge of control and the representative of the entity shall sign each page of the minutes which contain several pages.
- (4) The minutes shall be signed and verified by a seal of the entity under control, a signature of the director, that is, the directors of the entity under control, and a signature of the representative of the entity under control.
- (5) If the entity under control refuses to sign the minutes, the authorized person in charge of control shall list the reasons for the refusal.
- (6) The name and the surname of the authorized person in charge of control and the number of his/her identification card, the place, the day and the hour when the control has been conducted, the subject of the control, the persons present, the representative or the attorney-in-fact of the entity under control, the established actual situation, the comments, the statements, and the other relevant facts and circumstances shall be in particular stated in the minutes.
- (7) In the cases where irregularities are established in the minutes of the completed control, the authorized person in charge of control shall have the right and obligation, during the control, for the purpose of eliminating the irregularities, to the entity under control:
  - to point out the established irregularities and to set a deadline for their elimination,
  - to order it to take appropriate measures and activities within a deadline set by the authorized person in charge of control,
  - to file a motion for initiation of a misdemeanor procedure, or
  - to initiate another appropriate procedure.
- (8) The entity under control shall be obliged, within a period of three days, to inform the authorized person in charge of control whether it has acted upon the ordered measures from the control.

(9) Upon the expiry of the deadline referred to in paragraph (8) of this Article, repeated control shall be conducted of the part where violations and irregularities have been established and new minutes shall be prepared.

(10) On a request of the authorized person in charge of control, the entity under control should provide copies of the documentation that has been controlled, as attachment to the minutes.

## Complaint filed against the minutes

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### Article 39-h

(1) The entity under control may file a complaint against the minutes of the completed control within a period of eight days as of the day of receipt of the minutes of the completed control to the Ministry of Health.

(2) The minutes that contains established irregularities and for which no complaint is filed by the entity under control within the deadline set shall be final.

(3) If the subject under control files a complaint, the authorized person in charge of control who has conducted the control shall submit the minutes of the control and the complaint together with the complete documentation to the Ministry of Health for the purpose of taking further actions.

(4) Upon receipt of the complaint, the Ministry of Health shall review and determine whether it is justified, sent on time and signed by the authorized person of the entity under control.

(5) If the complaint is unjustified, not sent on time and not signed by the authorized person of the entity under control, the Ministry of Health shall inform the entity under control in writing that the complaint filed is not grounded.

(6) In the case where the Ministry of Health, at the time of checking the whole documentation, establishes that the complaint should be accepted and there is no need of conducting repeated control, it shall send a notification to the entity under control within a period of 15 days.

(7) If the Ministry of Health assesses that there is a need of repeated control of the entity based on the complaint, it shall be conducted within the shortest possible period.

(8) In the case where the irregularities established in the previous control are confirmed by the repeated control, a report shall be prepared within a period of 15 days for which the entity shall not have the right to file a complaint.

## Submission of the final minutes

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## Article 39-i

Upon completion of the procedure for control, a copy of the final minutes may be submitted for taking further actions to other authorized sectors in the Ministry of Health and competent institutions which conduct control of the lawfulness of the work of the entity and control of the professional work for the purpose of familiarizing or taking measures within their competence.

## Records of the controls conducted and measures imposed

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### Article 39-j

(1) Records of the controls conducted and measures imposed shall be kept in the Ministry of Health.

(2) The authorized person in charge of control shall prepare a monthly and quarterly report for the completed controls.

(3) On the basis of the monthly and the quarterly reports referred to in paragraph (2) of this Article, the Ministry of Health shall prepare an annual report for the completed regular and extraordinary controls and shall submit it to the Government of the Republic of Macedonia for information.

## Filing a motion for initiation of a misdemeanor procedure

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### Article 39-k

(1) If the authorized person in charge of control, in the course of conducting the control, establishes that a misdemeanor is committed, he/she shall be obliged, without any delay, to file a motion for initiation of a misdemeanor procedure.

(2) The competent body where the procedure referred to in paragraph (1) of this Article is initiated shall be obliged to inform the Ministry of Health about the course and the outcome of the procedure.

(3) If the authorized person in charge of control, in the course of conducting the control, establishes a misdemeanor for which an on-the-spot penalty is foreseen by law, he/she shall impose an on-the-spot penalty at the place of the misdemeanor.

## Referral of patients for specialist and consultative services by using medical equipment

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### Article 39-l

(1) The healthcare worker who renders specialist and consultative services shall be obliged to refer the patients to the secondary and tertiary level of health protection for specialist and consultative services by using medical equipment (hereinafter: referral of patients for



using medical equipment) through the electronic list of scheduled examinations and interventions and in accordance with the professional instructions for evidence-based medicine referred to in Article 27 paragraph (1) of this Law and the protocols referred to in Article 27 paragraph (4) of this Law.

(2) The healthcare worker who renders the specialist and consultative services referred to in paragraph (1) of this Article shall be held accountable for unfounded and unjustified referral of patients for specialist and consultative services by using medical equipment.

(3) The healthcare worker who renders specialist and consultative services shall be deemed to make an unfounded and unjustified referral of the patients for using medical equipment if:

- he/she refers the patients for specialist and consultative services by using medical equipment contrary to the professional instructions for evidence-based medicine referred to in Article 27 paragraph (1) of this Law and the protocols referred to in Article 27 paragraph (4) of this Law, and
- he/she refers the patients to diagnostic procedures for radiological diagnostics with computer tomography and magnetic resonance in accordance with the professional instructions for evidence-based medicine referred to in Article 27 paragraph (1) of this Law and the protocols referred to in Article 27 paragraph (4) of this Law, but absence of a disease and/or injury has been established by the conducted examinations in 20% of the total number of referrals for using medical equipment in the course of the preceding year, unless the patient is referred to diagnostic procedures for radiological diagnostics with computer tomography and magnetic resonance for the purpose of proving the absence of a disease and/ or injury in accordance with the professional instructions for evidence-based medicine.

(4) The grounds for, and the justification of, the referral referred to in paragraph (3) of this Article shall be monitored, assessed, and determined by the Ministry of Health based on the data from the electronic list of scheduled examinations and interventions and the report from the healthcare worker who renders specialist and consultative services and their comparison with the professional instructions for evidence-based medicine referred to in Article 27 paragraph (1) of this Law and the protocols referred to in Article 27 paragraph (4) of this Law.

(5) The healthcare worker rendering specialist and consultative services referred to in paragraph (1) of this Law, for whom the Ministry of Health establishes that he/she has made an unfounded and unjustified referral of the patients for using medical equipment in the cases referred to in paragraph (3) of this Article, shall attend training in the duration of 20 hours for the professional instructions for evidence-based medicine referred to in Article 27 paragraph (1) of this Law and the protocols referred to in Article 27 paragraph (4) of this Law, and training for familiarization with the features of the medical equipment, its use, and the harmful consequences arising from the unfounded and excessive use of the medical

equipment.

(6) The training referred to in paragraph (5) of this Article shall be organized by the Ministry of Health.

(7) Provided that the healthcare worker rendering specialist and consultative services referred to in paragraph (1) of this Article does not attend the training pursuant to paragraph (5) of this Article, he/she shall be disciplinary liable for a disciplinary offense and the management body of the public healthcare institution in which he/she is employed shall initiate a disciplinary procedure on the basis of a notification from the Ministry of Health.

(8) If the events referred to in paragraph (3) of this Article reoccur even after the trainings attended, the healthcare worker who provides specialist and consultative services referred to in paragraph (1) of this Article shall be disciplinary liable for a disciplinary offense and the management body of the public healthcare institution in which he/ she is employed shall initiate a disciplinary procedure on the basis of a notification from the Ministry of Health.

(9) In the events referred to in paragraphs (7) and (8) of this Article, the minister of health shall determine a contractual penalty pursuant to Article 104 paragraph (4) of this Law to the management body of the public healthcare institution in which the healthcare worker who provides specialist and consultative services referred to in paragraph (1) of this Article is employed which failed to implement a disciplinary procedure and to adopt a decision for imposing a disciplinary measure.

## Reference center

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### 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

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### Cooperation of the primary level healthcare institutions with other entities

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## 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

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### 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

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### 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 professional consultation for the complex professional 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

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

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##### 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, or
- 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.

## Requirements for provision of health services to foreigners who cover the costs for treatment by themselves

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### Article 44-a

(1) The health services in the healthcare institutions that provide health services to foreigners who cover the costs for treatment by themselves shall be rendered by a team headed by a healthcare worker – specialist who performs the intervention, that is, who conducts the diagnostic procedure, that is, who makes the specialist and consultative examination.

(2) The team headed by the healthcare worker – specialist referred to in paragraph (1) of this Article shall have the right to additional income, that is, remuneration for the rendered health service, which is not a part of the salary of the members of the team. The remuneration for the team for the rendered health service shall be paid from the price that the public healthcare institution charges from the patient – foreigner and shall amount 70% of the profit that the public healthcare institution generates from the charged price for the service rendered.

(3) The price for the health services that are rendered to foreigners shall be charged according to the price list adopted by the director of the healthcare institution, consent for which shall be granted by the minister of health.

## Records of the health services and purpose of the funds

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### 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

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##### 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

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##### 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 medications 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

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##### Healthcare activity in the field of public health

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##### 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

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### 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

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### 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

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### 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 fertilization procedures

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### Article 52

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

## Emergency medical care activity

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## 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

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### 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

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### 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

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### 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

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



## institutions

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### Establishment of healthcare institutions

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#### 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

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#### 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

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#### 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

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#### 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) *Abolished* 2

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(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 professional 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

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### 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 professional personnel including a list of people planned to be engaged, with data on their professional 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

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### 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 professional 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 professional personnel in the healthcare institution not to disturb the performance of the healthcare activity in the healthcare institution in the network wherefrom the professional 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) The request form referred to in paragraph (1) of this Article and the necessary documentation for the fulfillment of the requirements regarding the space and/or the equipment referred to in Article 60 of this Law shall be prescribed by the minister of health in accordance with the minister of information society and administration.

(8) 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 15 days as of the day of receipt of the decision to the State Commission for Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance.

## Contents of the license for work of the healthcare institution

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### 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

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### 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

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### 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 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

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### 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

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### 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

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### Determination of the types of healthcare institutions

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#### 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),
- hospital for special care,
- institute,
- university clinic,
- university 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

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### 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

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### 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

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### 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

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### 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

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### 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 medical care,
- preventive health protection for pre-school and school children,
- polyvalent 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 professional assistance, provided that there is no general hospital on its territory.

## Center

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### 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

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### 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

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### 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 medications to the patients treated in the hospital.

(4) 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

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### 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 medications to the patients treated in the hospital.

## Clinical hospital

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### 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

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### 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

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### 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

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### 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

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### 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 professional and medical doctrinaire criteria in its field.

## Institute of Labor Medicine

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### 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 professional 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 professional 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

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### 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

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### 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 professional, organizational, and technologically complex and multidisciplinary healthcare treatment of a particular branch of medicine, that is, dental medicine, it shall create and implement professional and medical doctrinaire criteria in its field, and it shall provide professional 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 employs at least five doctors of medicine, that is, doctors of dental medicine, 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

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### 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 and/or other requirements determined by 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 professional, 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 professional and medical doctrinaire criteria in its field and it shall provide professional and medical assistance to healthcare institutions of a corresponding branch of the medicine.

## University institute for positron emission tomography

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### Article 86-a

(1) The University Institute for Positron Emission Tomography of the Republic of Macedonia shall perform a healthcare activity, that is, diagnostics of metabolic dysfunction by using positron emission tomography, shall produce radiopharmaceutical preparations, shall perform a scientific and research activity, and shall participate in the education of professionals in the field of nuclear medicine, radiopharmacy, medical physics, and other medicine related sciences.

(2) The University Institute for Positron Emission Tomography of the Republic of Macedonia may perform an activity if it employs at least five doctors of medicine, that is, doctors of pharmacy and doctors of physics, at least two of whom are professors at a faculty of medicine, pharmacy, and/ or physics. 4

(3) The University Institute for Positron Emission Tomography of the Republic of Macedonia may also perform an activity if the professors referred to in paragraph (2) of this Article are employed at the university institute and at the higher education institution in the area of medicine, pharmacy, and/or physics, pursuant to the provisions in the field of labor relations and the employment contract.

## University clinical center

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### Article 87

(1) A university clinical center shall be a healthcare institution that as a rule provides health services that require professional, 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 medications 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

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### 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

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### Article 89

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

## 8. Joint provisions on healthcare institutions

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### General acts of healthcare institutions

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#### 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 professional 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

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#### 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:

- a division and a depot for medications of a polyclinic,
- a service and a depot for medications in a medical center,
- a department with divisions in a center,
- a unit with departments where divisions and a laboratory within the Institute of Public Health of the Republic of Macedonia may be organized,
- a unit with departments where divisions for carrying out a hospital healthcare activity, a unit for carrying out a specialist and consultative healthcare activity, a laboratory and a hospital pharmacy within a hospital and an institute may be organized,
- a unit with departments where divisions and a hospital pharmacy within a university institute and a university clinic may be organized, and
- clinic with units and a hospital pharmacy within the university clinic center.

(3) As an exception to paragraph (2) lines 6 and 7 of this Article, a clinic with units and a hospital pharmacy as internal organizational units may be established within the Public Health Institution University Clinic for Traumatology, Orthopedics, Anesthesiology, Reanimation and Intensive Treatment and an emergency center - Skopje.

(4) 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

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### 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 sub-specialist, or a doctor of dental medicine, specialist or sub-specialist, that is, a healthcare worker with a higher education in pharmacy with an appropriate specialty or sub-specialty,
- to have at least five 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, French, German), to have active knowledge in office computer programs, and to have other special work competencies determined by the act on systematization of jobs for the respective job.

(3) The following persons who meet the requirements referred to in paragraph (2) lines 2, 3, 4, 5 and 6 of this Article, in addition to a doctor of medicine, specialist or sub-specialist, or a healthcare worker with a higher education in pharmacy with an appropriate specialty or sub-specialty, may also manage the laboratories which are organized as units in the university institutes, the university clinics, and the clinics in the university clinical center:

- a healthcare co-worker with a higher education in biochemistry and physiology and molecular biology, with an appropriate specialty or sub-specialty training done at a higher education institution in the field of medicine;
- a healthcare worker with a higher education in biochemistry and physiology and molecular biology and a completed second or third cycle of studies in the field of healthcare activity or in the field of biochemistry and physiology and molecular biology, as well as
- a healthcare worker with a higher education in biochemistry and physiology and molecular biology, with an appropriate specialty or sub-specialty training done at a higher education institution in the field of medicine and a completed second or third cycle of studies in the field of healthcare activity or in the field of biochemistry and physiology and molecular biology.” 5

(4) Due to the need of a multidisciplinary approach when making a diagnosis and treating diseases, the units in the university institutes, the university clinics, and the clinics in the university clinical center, in which the healthcare services are performed by healthcare workers and healthcare co-workers, in addition to a doctor of medicine, a specialist or a sub-specialist, may also be managed by the following persons who meet the requirements referred to in paragraph (2) lines 2, 3, 4, 5, and 6 of this Article:

- a healthcare co-worker with a higher education in the field which is required by the multidisciplinary approach applied in the unit when making a diagnosis and treating diseases and an appropriate specialty or sub-specialty training done at a higher education institution in the field of medicine;
- a healthcare co-worker with a higher education in the field which is required by the multidisciplinary approach applied in the unit when making a diagnosis and treating diseases and a completed second or third cycle of studies in the field of healthcare activity, as well as
- a healthcare co-worker with a higher education in the field which is required by the multidisciplinary approach applied in the unit when making a diagnosis and treating diseases, an appropriate specialty or sub-specialty training done at a higher education institution in the field of medicine, and a completed second or third cycle of studies in the field of healthcare activity.

## Management and governance of private healthcare institutions

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### 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.

## Records of the medical equipment

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### Article 92-a

(1) The public healthcare institutions shall be obliged to keep records of the medical equipment that they have at their disposal and by means of which they carry out the healthcare activity.

(2) The records of the medical equipment referred to in paragraph (1) of this Article shall particularly contain data on: the type of the equipment, the description of the equipment, in which specialty, that is, sub-specialty it is used, whether scheduling via the electronic list of scheduled examinations and interventions is required for the use of the equipment, the year of production, the name of the producer, the year of procurement, the date of conclusion of the procurement contract, that is, of the donation contract and the archive number under which the contract has been entered, the purchase price of the medical equipment, the date of conclusion of the contract for maintenance of the medical equipment and the archive number under which the contract has been entered, the depreciation rate, the number of repairs done, the parts changed, and the degree of utilization.

(3) The records of the medical equipment referred to in paragraph (1) of this Article shall be kept continuously and every change shall be entered immediately upon its occurrence and within 12 hours at the latest.

(4) The public healthcare institutions shall enter the data from the records referred to in paragraph (1) of this Article in the integrated health information system established in accordance with the regulations in the field of health records, on a monthly basis.

(5) The manner of keeping the records of medical equipment, as well as the type, template, and contents of the forms for keeping the records of medical equipment referred to in paragraph (1) of this Article shall be determined by the minister of health.

(6) Upon the adoption of the bylaw referred to in paragraph (5) of this Article, the Ministry of Health shall be obliged to publish it immediately on the website of the Ministry and in the "Official Gazette of the Republic of Macedonia".

## Using the records of medical equipment

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### Article 92-b

(1) The records of medical equipment referred to in Article 92-a of this Law shall be used by the management body of the public healthcare institution for planning the use of the existing medical equipment and for planning the procurement of new medical equipment, as well as by the Ministry of Health.

(2) The director, that is, the directors of the public healthcare institution shall be obliged to use the data from the records of medical equipment referred to Article 92-a of this Law, as well as the data for the need of new medical equipment established based on the analysis of the data from the integrated health information system, when preparing the draft plan for public procurement of medical equipment.

## Responsibilities of the director and the healthcare workers in respect of the medical equipment

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### Article 92-c

(1) The director, that is, the directors of the public healthcare institution shall be obliged to make the medical equipment operational and to provide its use for the purpose of carrying out the healthcare activity by the healthcare workers rendering specialist and consultative activity and by the healthcare workers performing interventions and surgical interventions.

(2) The healthcare workers rendering specialist and consultative activity and the healthcare workers performing interventions and surgical interventions shall be obliged to use the medical equipment for carrying out the healthcare activity.

(3) The director, that is, the directors of the public healthcare institution shall be obliged to keep the medical equipment operational at any given time with the aim of providing continuity of the health protection and to maintain the medical equipment that is at the disposal of the public healthcare institution which is under their management.

(4) The director, that is, the directors of the public healthcare institution shall be obliged to make the malfunctioning medical equipment operational again within a period of one to seven days as of the day of occurrence of the malfunction, depending on the type of malfunction, and to provide the patients, who have had an appointment scheduled via the electronic list of scheduled examinations and interventions, with an examination or intervention by means of another medical equipment of the same kind within the same or another public healthcare institution, or to provide them with an examination or an intervention with the repaired medical equipment immediately after making it operational.

(5) The director, that is, the directors of the public healthcare institution shall be obliged to submit a written notification to the Ministry of Health of each malfunction of the medical equipment within a period of no more than 24 hours as of the time the malfunction occurred.

(6) The director, that is, the directors of the public healthcare institution shall be obliged to ensure that data on malfunction of a particular medical equipment is entered in the electronic list of scheduled examinations and interventions immediately after the occurrence of the malfunction.

(7) The people that keep, publish, and update the electronic list of scheduled examinations and interventions shall be obliged to enter the data that a particular medical equipment is malfunctioning immediately after the occurrence of the malfunction.

## National system for material-financial, and accounting operation in the public healthcare institutions

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### Article 92-d

(1) For the purpose of ensuring traceability of all medical consumables, medical devices, medications, and other materials procured by the public healthcare institution for treatment of patients (hereinafter: basic and auxiliary medical materials) by collecting data on the quantity and value of the basic and auxiliary medical materials and medications that are spent for the treatment of a single patient, that is, that are spent by a single healthcare worker and healthcare co-worker for the treatment of the patient, for the purpose of analyzing and monitoring the quantities and planning the procurement and planning the supplies of medical consumables, medical devices, medications, and all other materials that are procured by the public healthcare institution, as well as for the purpose of analyzing the financial effects of their consumption and monitoring the overall financial operation of the public healthcare institutions, a National System for Material-Financial and Accounting Operation in the Public Healthcare Institutions (hereinafter: the National System) which shall provide faster, easier and correct decision-making in the management of the finances and the other operation processes in the public healthcare institutions, monitoring the crucial aspects of the consumption, control, and reduction of the individual and overall costs in the public healthcare institutions shall be established.

(2) The data on the codes of the basic and auxiliary medical materials that are procured by the public healthcare institution, their EAN (European Article Number) codes, the codes for these materials of the Health Insurance Fund of Macedonia and their prices shall particularly be entered in the National System referred to in paragraph (1) of this Article.

(3) The National System shall be an integral part of the integrated health information system established in accordance with the regulations on records in the field of health.

(4) The public healthcare institutions shall be obliged to introduce regular record keeping of all basic and auxiliary medical materials spent which are classified per patient, referral, and healthcare worker, that is, healthcare co-worker, as well as mandatory records keeping of the medical material supplies in the main depot and in all the ancillary depots for medications.

(5) The following data shall be entered in the mandatory records of medical material supplies in the main depot and in all the ancillary depots for medications for the purpose of having exact information about the supplies of medications together with their expiration date, destruction of the medications with passed expiration date, timely provision of new supplies and protection of patients from taking inadequate medications:

- EAN (European Article Number) code of the medication,
- production date of the medication, and
- expiration date of the medication.

(6) The director of the public healthcare institution shall be obliged to organize the placement of labels containing barcodes of the manufacturer, that is, the holder of the approval for putting the medications into circulation, as well as to provide barcode readers for each depot for medications for the purpose of keeping the mandatory records of medical materials supplies referred to in paragraph (5) of this Article.

(7) The director of the public healthcare institution shall be obliged to ensure and organize, in the financial accounting system, all material documents to be given an account and to be recorded and a debit entry to be made in a financial order, and in particular the following material documents:

- the receipts of the suppliers and the transfer documents from the main depot;
- the internal receipts on the grounds of the transfer documents and the requisition forms/lists of the medical materials spent per patients and healthcare workers, that is, healthcare co-workers from the ancillary depots,
- price leveling documents,
- the return receipts, incoming and outgoing invoices, and
- the statements of the budgetary and the personal account.

(8) The works referred to in paragraph (7) of this Article shall be carried out by a responsible accountant, employed at the public healthcare institution.

(9) For the purpose of unobstructed operation of the National System, the director of the public healthcare institution shall be obliged to provide a software application which enables continuous two-way communication and exchange of data with the integrated health information system established in accordance with the regulations on records in the field of health.

(10) Records of the overall financial resources of the public healthcare institutions in the financial accounting, records of the revenues and expenditures per types and per internal organizational units within every healthcare institution, and records of the funds spent from the budgetary and from the personal account grouped at the level of the public healthcare institution, per types of healthcare institutions and altogether for all the public healthcare institutions shall be kept in the National System.

## Central System for Electronic Records of the Working Hours

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### Article 92-e

(1) The Ministry of Health shall implement and keep a Central System for Electronic Records of the Working Hours and Control of the Access to the Premises in the Public Healthcare Institutions (hereinafter: the Central System).

(2) The Central System shall be an information system which provides records of the arrival to, and departure from, work of the public healthcare institutions' employees, as well as records of their presence in the premises of the public healthcare institution, and in particular in the outpatient clinic, operating room, department, or in the premises for performing interventions or diagnostic procedures.

(3) The Central System shall contain the personal data of the employees in public healthcare institutions, the biometric data needed for verification of the identity of the person to whom the personal data belong, and data on the premises in the buildings where the public healthcare institutions are located.

(4) For the purpose of ensuring confidentiality and protection of the processing and maintaining of the personal data of the employees of the public healthcare institutions, appropriate technical and organizational measures for protection against accidental or illegal personal data destruction, or accidental loss, modification, unauthorized disclosure or access, particularly when the processing includes transfer of data through a network, and protection against any kind of illegal forms of processing, shall apply.

(5) The personal data of the employees of the public healthcare institutions referred to in paragraph (4) of this Law may be transferred through an electronic communication network, only if they are specially protected by appropriate technical and organizational measures, so that they are not readable during the transfer. The technical and organizational measures provide a level of protection of the personal data proportional to the risk present while processing them, as well as the nature of the data that are being processed.

(6) The description of the technical and organizational measures for ensuring confidentiality and protection of the personal data processing shall be determined by the minister of health.

(7) The Central System provides records of the arrival to, and the departure from, work of the employees of the public healthcare institutions, as well as records of their presence in the premises of the public healthcare institution by checking the personal identity of the employees of the public healthcare institutions using a scanner with biometric sensor installed in the facilities where the public healthcare institutions are located.

(8) Every public healthcare institution shall have access to the data from the records of the arrival to, and the departure from, work and to the data from the records of the presence in the premises of the public healthcare institution for the employees of that public healthcare institution and shall not have the right to access to these data for the employees of other public healthcare institutions.

(9) The manner of keeping the records of the arrival to, and the departure from, work of the employees of the public healthcare institutions and the records of their presence in the premises of the public healthcare institution, as well as the manner of checking the personal identity of the employees of the public healthcare institutions using a scanner with biometric sensor, and the type of biometric data used for that purpose shall be determined by the minister of health.

(10) Following the adoption of the bylaw referred to in paragraph (9) of this Article, the Ministry of Health shall be obliged to publish it immediately on the website of the Ministry and in the "Official Gazette of the Republic of Macedonia."

## Day hospital

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### 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

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### 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

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### 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

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### 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 primary schools for children with special educational needs may implement particular measures under the healthcare activity at primary level for their students.
- (4) 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.
- (5) Hotels with capacity of more than 100 beds shall mandatorily organize a healthcare point as an internal organizational unit.
- (6) 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.
- (7) The location of the healthcare points referred to in paragraph (5) of this Article shall be determined by the minister of health.
- (8) 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.
- (9) The healthcare services provided at the healthcare points shall not be covered by the Fund.

#### Article 96-a

- (1) The legal entities shops specialized for retail sale of medical devices, entered in the register of shops specialized for medical devices, and the legal entity – trade companies doing business in ocular optics may carry out a healthcare activity optometry, provided that they possess an appropriate equipment for carrying out such a healthcare activity and have employed a full-time optometrist referred to in Article 15, point 36 of this Law for an indefinite period of time.
- (2) The space, the equipment and the staff necessary for carrying out the healthcare activity referred to in paragraph (1) of this Article shall be determined by the minister of health.



(3) The health services provided in the legal entities referred to in paragraph (1) of this shall not be born 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

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## Meeting the public interest

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### 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

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### 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

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### 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 professional and competent persons in the public

healthcare institution elected by the professional 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

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### 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,

medications, 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

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### 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

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### Article 103

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

## Management body

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### 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 or dental or pharmacy sciences, a higher education - a graduated speech therapist, a higher education - specialist in medical biochemistry, 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 a healthcare institution, that is, in the economy, finances, law or management or in the system and organization of the health protection and health insurance and a passed director examination;
- 5) to offer a work program for the public healthcare institution of the highest quality; and
- 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.

(3) As an exception to paragraph (2) of this Article, if improvement of the operation of the healthcare institutions is needed by transfer of skills and knowledge in the field of medicine and management of healthcare institutions, a person who, in addition to the general requirements set out in the regulations in the field of movement, stay and employment of foreigners, meets the following requirements:

- 1) to be a citizen of an OECD member state,
- 2) at the moment of appointment, not to be issued a penalty or misdemeanor sanction banning him/her from exercising a profession, business or office by an effective court ruling in the country of citizenship, in another OECD member state, or in the Republic of Macedonia;
- 3) to have completed the first, second and/or third cycle of studies abroad in the field of medical or dental sciences, that is, pharmacy or a higher education abroad in the field of economic or legal sciences, public healthcare management or completed academic studies abroad, and
- 4) to have at least five years of work experience in a healthcare institution in an OECD member state at managerial position, may be appointed a director.

(4) The rights and obligations between the director, the acting director and the employer shall be regulated by a managerial contract that shall particularly contain indicators of success that the director should achieve.

(5) The managerial contract shall particularly contain provisions on contractual penalty for violation 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 200 in Denar counter-value, or Euro 50 to 200 in Denar counter-value for a period of one to six months. The cases of violation of the managerial contract where contractual penalty and the amount of the contractual penalty is determined may be also laid down by this Law.

(6) The managerial contract referred to in paragraph (3) of this Article shall be verified by a competent notary and it shall contain an enforcement clause.

(7) The director, that is, the acting director shall be obliged to act upon orders, instructions, plans, and programs adopted by the minister of health, which order or prohibit taking actions in a particular situation of general importance to the implementation of the laws and bylaws, which prescribe the manner of taking actions in the implementation of particular provisions of the laws and bylaws, that is, which determine and elaborate particular issues regarding the implementation of the laws and bylaws which require setting deadlines and a time-schedule for their implementation.

(8) The non-observance of the obligation referred to in paragraph (6) of this Article shall constitute a violation of the managerial contract by the director.

## Contractual penalty

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### Article 104-a

"(1) Contractual penalty in the amount of Euro 200 in Denar counter value shall be imposed on the director if the healthcare worker, that is, healthcare co-worker who works with patients, during his/her working hours does not wear a tag in a visible place containing the name, the position and the healthcare institution where he/she works pursuant to Article 169 of this Law, that is, contractual penalty in the amount of Euro 200 in Denar counter value shall be imposed if he/she fails to initiate a disciplinary procedure for a disciplinary offense against the healthcare worker, that is, healthcare co-worker who does not wear a tag in a visible place containing the name, the position and the healthcare institution where he/she works within a period of seven day as of the day he/she became familiar with the reason for initiating the disciplinary procedure pursuant to Article 169 of this Law. 6

(2) Contractual penalty in the amount of Euro 200 in Denar counter value shall be imposed on the director if payment of the salary of the healthcare worker is made based on false and unauthentic information regarding the work results of the healthcare workers entered in the integrated health information system.

(3) Contractual penalty in the amount of Euro 200 in Denar counter value shall be imposed on the director if he/she fails to initiate a disciplinary procedure for a disciplinary offense against the head of the internal organizational unit and the healthcare worker who have determined or entered false and/or unauthentic data contrary to Article 219 paragraphs (3) and (4) of this Law.

(4) Contractual penalty in the amount of Euro 200 in Denar counter value shall be imposed on the director if he/she fails to initiate a disciplinary procedure for a disciplinary offense and/or fails to adopt a decision imposing a disciplinary measure on the healthcare worker who renders specialist and consultative services referred to Article 39-I paragraph (1) of this Law, who has not attended training for familiarization with the features of the medical equipment, its use, and the harmful consequences arising from the unfounded and excessive use of the medical equipment, as well as who despite the trainings attended continues to refer patients to secondary and tertiary level of health protection for using medical equipment contrary to the professional instructions for evidence-based medicine referred to in Article 27 paragraph (1) of this Law and the protocols referred to in Article 27 paragraph (4) of this Law, and/or absence of a disease and/or injury in 20% of the total number of referrals for using medical equipment during a month has been established by the conducted examinations.

(5) Contractual penalty in the amount of Euro 200 in Denar counter value shall be imposed on the director if, within the deadlines set out in Article 193-a paragraphs (8) and (9) of this Law, the complainant referred to in Article 193-a paragraph (1) of this Law expressing his/her discontent due to the non-application and non-observance of the principles and rules governing the behavior and operation determined by the minister of health by a rulebook of hospital culture pursuant to Article 27 paragraph (5) of this Law by the healthcare workers and healthcare co-workers fails to receive a notification about the establishment of a commission for conducting a disciplinary procedure for the disciplinary offense, that is, fails to receive a decision imposing a disciplinary measure for a disciplinary offense on the healthcare worker, that is, healthcare co-worker who is disciplinary liable pursuant to Article 152-a paragraph (2) of this Law.

## Duty of a director performed by two persons

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### 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:
  - 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, and
  - APTIS - at least B2 level.

(3) As an exception to paragraph (2) of this Article, if improvement of the operation of the healthcare institutions is needed by transfer of skills and knowledge in the field of medicine and management of healthcare institutions, a person who, in addition to the general requirements set out in the regulations in the field of movement, stay and employment of foreigners, meets the following requirements:

- 1) to be a citizen of an OECD member state,
- 2) at the moment of appointment, not to be issued a penalty or misdemeanor sanction banning him/her from exercising a profession, business or office by an effective court ruling in the country of citizenship, in another OECD member state, or in the Republic of Macedonia;
- 3) to have completed the first, second and/or third cycle of studies abroad in the field of medical or dental sciences, that is, pharmacy; and
- 4) to have at least five years of work experience in a healthcare institution in an OECD member state at managerial position,  
may be appointed a medical director.

(4) 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.

(5) 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:
  - 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, and
  - APTIS - at least B2 level.

(6) As an exception to paragraph (4) of this Article, if improvement of the operation of the healthcare institutions is needed by transfer of skills and knowledge in the field of medicine and management of healthcare institutions, a person who, in addition to the general requirements set out in the regulations in the field of movement, stay and employment of foreigners, meets the following requirements:

- 1) to be a citizen of an OECD member state;
- 2) at the moment of appointment, not to be issued a penalty or misdemeanor sanction banning him/her from exercising a profession, business or office by an effective court ruling in the country of citizenship, in another OECD member state, or in the Republic of Macedonia;
- 3) to have completed the first, second and/or third cycle of studies abroad in the field of economic or legal sciences, public healthcare management or other academic studies abroad; and
- 4) to have at least five years of work experience in a healthcare institution in an OECD member state at managerial position,  
may be appointed an organizational director.

(7) 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.

(8) 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 procurement 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.

(9) 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.

(10) 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

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### 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, and the amount of such costs shall be determined by taking into consideration the costs for organization and delivery of the training for taking the examination for a director of a public healthcare institution in accordance with the program for taking the examination, the number of modules of such program, and the remuneration for the members of the examination commission for conducting the examination.. Z

(4) The contents of the program and the manner of scoring the first and the second part of the examination, as well as the amount of the costs for preparation of the candidate for a director for taking the examination for a director and the amount of the costs for taking the examination, the form and the contents of the certificate form shall be prescribed by the minister of health, in concurrence with the minister of finance.

## Taking a director examination in several parts

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### 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 of the candidates 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

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### Article 106-b

(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 representative 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 two times 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) Based on the completed review and update of the questions databases and the case study databases, the commission shall decide to amend or completely remove or replace by new ones at least 30% of the questions and the case studies from the databases referred to in paragraph (1) of this Article.

(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

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### Article 106-c

(1) The professional and administrative activities necessary for conducting the examination shall be carried out by the Ministry of Health, for the purpose of which the minister of health shall designate a responsible person who is to establish whether the candidate

meets the requirements for taking the examination, 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.

(2) The responsible person referred to in paragraph (1) of this Article shall be entitled to remuneration in the amount of one third of the average net salary in the Republic of Macedonia and the Ministry of Health shall adopt a decision thereof.

## Recording of the course of the director examination

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### Article 106-d

(1) The examination shall be held in premises for holding an examination, specially equipped for holding 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 holding 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 holding the examination.

(5) The representatives referred to in paragraph (4) of this Article shall be entitled to remuneration for every examination held in the amount of one third of the average net salary in the Republic of Macedonia and the Ministry of Health shall adopt a decision thereof.

(6) The authorized legal entity which conducts the examination technically shall be obliged to block the radio frequency range in the premises for holding the examination during the examination.

(7) The Agency for Electronic Communications (hereinafter: AEC) shall continuously monitor the blocking of the radio frequency range in the premises for holding the examination in order to prevent any kind of electronic communication with the surrounding outside the premises for holding the examination.

(8) AEC shall install measurement equipment in the premises for holding the examination which shall provide electronic record of the measurements made in duration of 30 days and they shall be stored in the central control system of AEC.

(9) AEC shall form a three-member commission which shall prepare a report based on the electronic records stored in the central control system of AEC and it shall deliver it to the Ministry of Health within a period of 15 days as of the completion of the examination at the latest.

## Rules of behavior in the course of the director examination

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### 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 and he/she shall be imposed a prohibition on taking the examination for directors in duration of three years, and the Ministry of Health shall adopt a decision thereof against which an administrative dispute may be initiated before a competent court within a period of 30 days as of the day of receipt of the decision.

(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

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### 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: 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 studies 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

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### 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.
- (4) The electronic system referred to in Article 106-f of this Law cannot allow the existence of an identical content of an electronic test for the first part of the examination, that is, an electronic case study for the second part of the examination at a single session for more than one candidate.

## Discontinuation, continuation and rescheduling of the director examination

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### 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

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### 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 the case study 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

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### 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

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### 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.

The commission referred to in paragraph (3) of this Article shall meet after every examination held and shall review the manner of conducting the examination, including whether the examination has been taken by candidates who meet the requirements for taking the examination in accordance with Article 104 paragraph (2) and Article 105 paragraphs (2) and (4) of this Law, and shall submit a report to the minister of health thereof.

The members of the commission referred to in paragraph (3) of this Article shall be entitled to remuneration which, at annual level, amounts one average net salary in the Republic of



Macedonia, and the Ministry of Health shall adopt a decision thereof.

(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

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### 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

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### 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

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### 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

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### 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 medications, 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

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### 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 specialty, that is, sub-specialty training out of the funds of the healthcare institution;
- 7) if he/she does not implement the recommendations of the professional 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;
- 11) if he/she does not submit a regular six-month report on the work;
- 12) if a complaint pursuant to Article 193-a of this Law has been filed to the director of the healthcare institution for two consecutive or three times in the course of a year, but he/she

fails to establish a commission for conducting the disciplinary procedure for the disciplinary offense, nor adopts a decision imposing a disciplinary measure,

13) if the data required for measuring the key success indicators are not entered for two consecutive or three times in the course of a year in the integrated health information system in accordance with the regulations in the field of health records within the time period and in the manner pursuant to Article 239-b paragraph (2) of this Law or if incorrect or unauthentic data required for measuring the key success indicators are entered, and  
14) if he/she fails to pay the contractual penalty referred to in Article 239-c paragraph (4) of this Law twice the amount pursuant to Article 239-c paragraphs (7), (8), or (9) of this Law, within the additional time period set out in Article 239-c paragraph (4) of this Law.

(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) In the cases referred to in paragraph (1) points 12) to 15) of this Article, the minister of health shall dismiss the director for whom the existence of grounds for dismissal are established, within a period of 15 days as of finding out the grounds for dismissal, that is, within a period of 15 days as of expiry of the additional time period referred to in Article 239-c paragraph (4) of this Law.

(4) 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.

(5) 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

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### 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 medications, 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

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## 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

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### 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

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

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#### Healthcare workers and co-workers for a healthcare activity

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##### 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 professional 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 professional examination.

(3) Particular health services under the healthcare activity may be independently provided by healthcare workers with appropriate specialty, that is, sub-specialty, and with a license for work, as well as healthcare co-workers with appropriate specialty, that is, sub-specialty, 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 professional 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

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### 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 professional examination,
- data on specialty, that is, sub-specialty 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

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### Article 117

(1) The healthcare institutions may admit healthcare workers, that is, healthcare co-workers on probationary work and training for taking the professional examination. The healthcare workers with a university degree, as well as the healthcare workers with a high school, two-year post secondary school and higher vocational degree shall acquire part of the probationary work and the training for taking the professional examination through which practical knowledge and skills are acquired at the Medical Simulation Center through training at equipment which simulates human pathological conditions and enables examination of the acquired skills through diagnostic and therapeutic interventions done at the equipment, on real cases given randomly, where at the same time video recording of the whole course of the intervention is made.

(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) As an exception to paragraph (3) of this Article, a probationary work of a healthcare worker with a university degree in the field of optometry and ocular optics shall be considered at least 15 years of work experience as an optician in an ocular optics in production and/or sale of optic devices and equipment or at least two years of work experience in carrying out a healthcare activity referred to in Article 26 paragraph (1) line (28) of this Law under the supervision of a doctor of medicine specialist in ophthalmology.

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

## Plan and program for probationary work of healthcare workers

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## 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 professional examination, and the form of the certificate for a passed professional examination shall be determined 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 professional examination, and the form of the certificate for a passed professional examination shall be determined by the minister of health.

(4) After the adoption of the bylaws referred to in paragraphs (2) and (3) of this Article, the Ministry of Health shall be obliged to immediately publish them on the website of the Ministry and in the "Official Gazette of the Republic of Macedonia".

## Educator for probationary work

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### 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

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### 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 specialty, 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.

## Professional examination for healthcare workers and co-workers

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### Article 121

(1) Upon completion of the probationary work, the healthcare workers and the healthcare co-workers shall be obliged to take a professional examination within a period of one year as of the day of completion of the probationary work plan and program or by meeting the requirements referred to in Article 117 paragraph (4) of this Law regarding the optometrists.

(2) If the healthcare workers and the healthcare co-workers do not take a professional 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 professional examination before examination commissions formed by the Doctors', Dental, that is, Pharmaceutical Chamber.

(4) The professional 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 examination commission referred to in paragraph (3) of this Article shall be composed of five members who are doctors of medicine, that is, pharmacy, that is, dental medicine, who have published at least five impact factor scientific papers and who have spent at least three months of training in the course of the last five years in the OECD member countries. The members of the commission shall have deputies who meet the same requirements as the members of the commission. 8

(6) The application for taking the professional examination shall be filed to the Doctors', Dental, that is, Pharmaceutical Chamber at least a month prior to being taken and the

Chamber shall approve the taking of the professional examination and shall determine the date of taking the examination. A certificate for completed higher education in the field of medicine, that is, dental medicine, or pharmacy and a certificate of the completed probationary work shall be also attached to the application for taking the professional examination.

(7) The healthcare worker taking the professional examination shall be obliged to use professional literature which is used at the world's top ten higher education institutions in the field of medicine, ranked at the last list published by the Center for World - Class Universities at Shanghai Jiao Tong University.

(8) The professional examination shall consist of the following three parts:

- first part, which is taken in a written form and by which the theoretical knowledge of the healthcare worker is checked,
- second part, which is taken in an oral form and by which the theoretical knowledge of the healthcare worker is checked, and
- practical part, by which the ability of the healthcare worker to apply the gained theoretical knowledge into practice is checked.

(9) The first part of the professional 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, computer-generated, the contents of which, by means of random choice, is determined by the software from the question database 15 minutes prior to the commencement of the examination at the most, by choosing one correct answer out of the five options offered, one of which is correct, two are similar, and two are incorrect, and by doing case studies, randomly chosen by the software from the case studies database.

(10) The second part of the professional examination shall be taken, as a rule, the following day after the successful passing of the first part, and no later than three days as of the day the first part of the professional examination has been held when the healthcare worker has successfully passed the first part. The taking of the second part of the professional examination shall be done by giving oral answers to the computer awarded questions given to the healthcare worker by means of random choice by the software from the question and case studies database, 15 minutes prior to the beginning of this part of the professional examination at the most.

(11) The practical part of the professional examination shall be taken, as a rule, the following day after the successful passing of the second part, and no later than five days as of the day the second part of the professional examination has been held when the healthcare worker has successfully passed the second part.

(12) The question database for the first and second part of the professional examination shall be prepared by a commission established by the minister of health, the members of which meet the requirements referred to in paragraph (5) of this Article and it shall contain 4.000 questions at the least, which are from the professional literature used at the 100 world's top higher education institutions in the field of medicine, dental, that is, pharmaceutical sciences, ranked at the last list published by the Center for World - Class Universities at Shanghai Jiao Tong University, as well as at least 1.500 case studies,. 9

(13) The first and the second part of the professional examination shall be taken in premises equipped especially for holding the examination with material, technical, and IT equipment, internet connection, and equipment for recording the course of the examination. The taking of the first and the second part of the professional 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. The taking of the third part of the professional examination shall consist of examination of the knowledge and the skills in the Medical Simulation Center where video recording is made of the whole course of the intervention, as well as examination of the knowledge and the skills on a real patient in an outpatient clinic, a hospital room, or at premises for interventions, which is not recorded.

(14) At the premises for holding the professional examination only the president, the members, and the secretary of the examination commission may be present in the course of the first part of the professional examination, and the second part of the professional examination shall be public.

(15) Exceeding the duration of the examination while taking the professional examination shall mean that the examination is not passed.

(16) The healthcare worker who has not passed the first or the second part, that is, the practical part of the professional examination shall have the right to retake that part within a period of 30 days at the least, and 60 days at the most as of the day the taking of that part of the professional examination has been carried out for the first time.

(17) The healthcare worker who has not passed the professional examination shall have the right to take the examination once more. If the healthcare worker fails to pass the professional examination again, he/she shall redo the probationary work.

(18) If the healthcare worker fails to pass the professional examination within a period of one year as of the completion of the plan and program for probationary work, he/she shall lose the right to take the professional examination, except in the events of a longer leave due to illness or injury, as well as prevention to work due to pregnancy, childbirth and maternity.

(19) The forms of the certificate for a passed professional 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, and the forms of the certificate for a passed professional 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 determined by the minister of health.

(20) The manner of applying for taking the professional examination and the manner of taking the professional examination for healthcare workers with a university degree, the number of questions and practical cases, the duration and the number of scores for considering the professional examination passed, the submission of a complaint by the healthcare worker who has not passed the professional examination, and the manner of issuing the certificate for a passed professional examination, as well as the form and the contents of the certificate for a passed professional examination of the healthcare workers with a university degree, shall be determined by the minister of health upon a previous opinion of the Doctors', Dental, that is, Pharmaceutical Chamber.

## Recognition of the probationary work and the professional examination taken and passed abroad

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### Article 122

(1) The probationary work and the professional 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 professional examination does not differ from the probationary work program, that is, the program for professional examination adopted on the basis of this Law.

(2) The recognition of the probationary work and the professional 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

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### Competence of the chambers

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### 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 professional competence of the healthcare workers for independent work.

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

(3) As an exception to paragraphs (1) and (2) of this Article, the Doctors' Chamber shall, in cooperation with the Ministry of Health, issue a temporary license for work to the doctors of medicine, specialists, that is, sub-specialists from the OECD member countries or Macedonian citizens, who have worked continuously for a period of five years in healthcare institutions, that is, higher education institutions in the field of medicine in the OECD member countries, as well as heads of healthcare institutions in the OECD member countries, with whom, pursuant to the regulations in the field of medical studies and continuous professional development of the doctors of medicine, the Ministry of Health has concluded a contract for performing a healthcare activity as a healthcare worker in a public healthcare institution with the purpose of developing the skills and knowledge of the doctors of medicine, specialists, and sub-specialists in the public healthcare institutions in the Republic of Macedonia through transfer of skills and knowledge in the field of medicine and operation in the healthcare institutions. These doctors of medicine do not have to undergo additional training and check of the professional knowledge and skills determined in the program in Article 126 paragraph (1) of this Law, and they also do not have to meet the requirement set out in Article 128 of this Law of possessing a good command of the Macedonian language. The temporary license for work shall be issued for the period for which the contract for performing a medical activity as a healthcare worker at a public healthcare institution is concluded, and which terminates the day following the day of expiry of the period for which the contract is concluded.

## Obtaining a license

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### 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 professional examination.

(2) A healthcare worker with a university degree, who has completed the probationary work and has passed the professional 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 professional 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 specialty and sub-specialty branch

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### Article 125

The healthcare worker with a university degree, upon completion of the corresponding residency, that is, sub-residency, may obtain a license for work in the corresponding specialty, that is, sub-specialty branch.

## Obtaining a license for a healthcare worker – foreign citizen

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### 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 has the professional knowledge and skills checked in accordance with the Program for Additional Training and Check of the Professional 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 professional 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 professional knowledge and skills

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### Article 127

(1) The program for additional training and check of the professional 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

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### 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

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### 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) The work in a dental health protection of a healthcare worker with a university degree in the field of dental medicine, on his/her request, may be calculated in at least 60% of the validity period of the license for work.

(3) 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.

(4) 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

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## 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 professional knowledge and skills in accordance with the Program for Additional Training and Check of the Professional 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

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### 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 professional knowledge and skills before an examination commission of the corresponding chamber.

## Temporary or permanent revocation of the license

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### 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 professional 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 professional knowledge and skills before an examination commission of the corresponding chamber in order to be reissued 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

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### 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

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### 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 professional 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 professional 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

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### 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

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### 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

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#### Requirements for awarding the title of primarius

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##### 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 professional 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. Specialties and sub-specialties

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#### Right to specialty and sub-specialty

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##### Article 138

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

(2) The branches of specialties and sub-specialties in the field of medicine, the training duration, the parts of the residency (modules), the curricula, 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.

(3) The branches of specialties and sub-specialties in the field of dentistry and pharmacy, as well as the branches of specialties and sub-specialties of healthcare workers, the training duration, the parts of the residency (modules), the curricula, 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.

(4) The bylaw referred to in paragraph (2) of this Article shall prescribe the specialty in outpatient emergency medicine in duration of 36 months (hereinafter: outpatient emergency medicine in duration of 36 months) where healthcare workers with a university degree in the field of medicine employed in the emergency services in the public healthcare institutions shall have the right to apply.

(5) The doctors in general medicine who work as chosen doctors in accordance with Article 32 of this Law and the doctors in general medicine who work at the chosen doctors, provided that they have at least three years of work experience as chosen doctors, shall have the right to apply for specialty in outpatient pediatrics in duration of 36 months (hereinafter: outpatient pediatrics in duration of 36 months) and afterwards they shall be granted a license for carrying out a healthcare activity in the network at primary level of health protection as a chosen doctor specialist in pediatrics without conducting the procedure for granting the license referred to in Article 229 of this Law.

(6) The doctors of medicine specialists in outpatient emergency medicine and the doctors of medicine specialists in outpatient pediatrics referred to in paragraph (5) of this Article, shall have the right, after completing the specialty in outpatient emergency medicine in duration of 36 months, that is, outpatient pediatrics in duration of 36 months, to additionally do parts of the residency in emergency medicine, that is, hospital pediatrics that are not covered by the curricula for outpatient emergency medicine in duration of 36 months, that is, outpatient pediatrics in duration of 36 months after which they shall acquire a professional title of a specialist in emergency medicine, that is, a specialist in hospital pediatrics based on a decision of the higher education institution that delivers the specialty, adopted on a request of the specialist (right of passing).

## Manner of carrying out

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### Article 139

The specialty and sub-specialty training of healthcare workers with a university degree and healthcare co-workers with a university degree shall be carried out in accordance with the curricula referred to in Article 138 paragraph (2) of this Law.

## Manner of delivery

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## Article 140

(1) The specialty and the sub-specialty training shall be delivered through theory classes and practical training during specific period of time in the corresponding higher education and healthcare institutions.

(2) The amount of the compensation for conducting the specialty, that is, sub-specialty training referred to in paragraph (1) of this Article shall be determined by the Government of the Republic of Macedonia on a proposal of the minister of health based on the amount of the compensation for:

- the actual material costs for the delivery of the theory classes referred to in paragraph (1) of this Article and for the persons engaged in the delivery of the theory classes;
- the actual material costs for conducting the practical training referred to in paragraph (1) of this Article and for the persons engaged in the delivery of the practical training; and for
- taking the preliminary examinations, intermediate examination, specialty, that is, sub-specialty examination.

(3) The higher education institution and the healthcare institution shall be obliged to use the funds that they receive for delivery of the specialty, that is, sub-specialty training for development of the higher education, that is, healthcare activity, for payment of the remuneration for the mentor and the educators, for covering the costs for studying foreign languages, and for carrying out the testing of the residents' foreign languages knowledge.

(4) The public healthcare institution which sends the healthcare workers and co-workers with a university degree to specialty and sub-specialty training shall pay the funds from the compensation referred to in paragraph (2) of this Article for all of the residents at the account of the higher education institution where the specialty, that is, sub-specialty training is delivered, on the basis of a previously concluded contract between the public healthcare institution and the higher education institution within a period of a month as of the day of adoption of the specialty, that is, sub-specialty training curriculum and before the funds from the compensation referred to in paragraph (2) of this Article are paid.

(5) The higher education institution shall keep 50% of the funds for compensation for each individual resident, that is, sub-specialty trainee earmarked for the delivery of his/her specialty, that is, sub-specialty training, and the other 50% of the funds for compensation for each individual resident, that is, sub-specialty trainee shall be appropriately distributed and paid to the public healthcare institutions where particular skills under the specialty, that is, sub-specialty training curriculum are being acquired and gained, based on a previously concluded contract with each public healthcare institution individually.

(6) The higher education institution where the specialty, that is, sub-specialty training is delivered shall be obliged to conclude the contracts with the public healthcare institutions referred to in paragraph (5) of this Article within a period of two months as of the day of

adoption of the specialty, that is, sub-specialty training curriculum before the payment of the funds from the compensation referred to in paragraph (2) of this Article, pursuant to paragraph (5) of this Article.

(7) Out of the funds that, in accordance with paragraph (4) of this Article, are received by the higher education institution for delivery of specialty training pursuant to paragraph (4) of this Article, the mentor shall be entitled to remuneration in the amount of 90% from the funds that the higher education institution receives for each resident, that is, sub-specialty trainee who is under his/her mentorship, and 10% shall be intended for the higher education institution for development of the higher education activity. The remuneration for the mentor shall be paid on the basis of a contract concluded between the higher education institution and the mentor.

(8) Out of the funds that, in accordance with paragraph (4) of this Article, are received by the public healthcare institution where particular skills under the specialty, that is, sub-specialty training curriculum are acquired and gained, the educator shall be entitled to remuneration in the amount of 60% of the funds that the public healthcare institution receives for each individual resident, that is, sub-specialty trainee who is under the guidance of that particular educator, and the public healthcare institution shall keep 30% of the funds that it receives for each individual resident, that is, sub-specialty trainee for covering the material costs incurring from his/her specialty, that is, sub-specialty training, and 10% shall be allocated for promotion and development of the healthcare services in the public healthcare institution. The remuneration for the educator shall be paid on the basis of a contract concluded between the public healthcare institution and the educator.

(9) The amount of the compensation for delivery of specialty, that is, sub-specialty training of the healthcare workers, that is, healthcare co-workers, enrolled pursuant to Article 150 of this Law, shall be 20% lower than the compensation paid by the public healthcare institutions for the healthcare workers with a university degree, that is, healthcare co-workers with a university degree employed in the public healthcare institution, that is, reduced for the amount of the funds that, pursuant to paragraph (8) of this Article, are received by the public healthcare institution where the specialty training is delivered for the purpose of compensating the material costs incurring from the specialty, that is, sub-specialty training and for promotion and development of the healthcare services in the public healthcare institution. The public healthcare institution where the specialty, that is, sub-specialty training of healthcare co-workers is delivered, that is, where the healthcare co-workers are enrolled pursuant to Article 150 of this Law shall be paid compensation solely for the persons engaged in the delivery of the practical training.

(10) The amount of the compensation for conducting the theory classes, the practical training and the taking of the specialty examination of the doctors of medicine enrolled in specialty in outpatient emergency medicine in duration of 36 months in accordance with Article 138 paragraph (4) of this Law and the doctors in general medicine enrolled in



specialty in outpatient pediatrics in duration of 36 months in accordance with Article 138 paragraph (5) of this Law, shall be determined in a manner and by taking into consideration the criteria referred to in paragraph (2) of this Article and it cannot be more than 30% of the amount of the compensation for specialty in emergency medicine, that is, in hospital pediatrics.

(11) For the purpose of delivering the specialty training in outpatient emergency medicine in duration of 36 months, that is, outpatient pediatrics in duration of 36 months, the Government of the Republic of Macedonia, on a proposal of the Ministry of Health, shall adopt a program for specialty training in outpatient emergency medicine and in outpatient pediatrics, the two of them in duration of 36 months, which shall provide financial funds for payment of the compensation for delivery of theory classes, the practical training and the taking of the specialty examination in the amount necessary for delivery of such specialty training.

(12) The Ministry of Health shall submit a draft program to the Government of the Republic of Macedonia regarding the specialty training in outpatient emergency medicine and outpatient pediatrics, the both in duration of 36 months based on the number of doctors of general medicine who are interested at enrolling in specialty training in outpatient emergency medicine, that is, in outpatient pediatrics, and who have applied at the public announcement which is published by the Ministry of Health once in a year on its website. It shall be required in the public announcement that doctors in general medicine from all statistical regions in accordance with the network of healthcare institutions, from all municipalities and cities in the Republic of Macedonia to apply in order to ensure geographical, physical and economic availability of health protection on the whole territory of the Republic of Macedonia. The number of doctors in general medicine for whom financial funds for payment of the compensation for specialty training in outpatient emergency medicine in duration of 36 months, that is, in outpatient pediatrics in duration of 36 months are to be provided cannot be higher than the amount of the available funds in the special program referred to in paragraph (11) of this Article. In the case of higher number of interested doctors in general medicine who meet the requirements referred to in Articles 138, paragraphs (4) and (5) and 141 of this Law who have applied at the announcement, in the course of selection of these for whom financial funds are to be provided, care shall be taken to ensure geographical, physical and economic availability of health protection of the children in all statistical regions in accordance with the network of healthcare institutions, and if there are more interested for one and the same region, they shall be ranked according to the following criteria, that is, 70% of the points for the average achievement of the interested person achieved at the university, 20% of the achievement in the subject in the field in which specialty training is granted and 10% for the length of service. The ponder of the points for the average achievement of the candidate achieved at the university and the achievement in the subject shall be calculated in the manner determined by the minister of health by the bylaw referred to in Article 149 paragraph (4) of

this Law. After the adoption of the program referred to in paragraph (11) of this Article, the Ministry of Health shall submit a list of doctors in general medicine to the higher education institution that delivers the specialty training for the purpose of their enrolling in the specialty training in outpatient emergency medicine in duration of 36 months, that is, in outpatient pediatrics in duration of 36 months.

(13) The theory classes, as well as the practical part of the residency in outpatient pediatrics in duration of 36 months done in a university clinic for children diseases, a university clinic for children surgery and a public healthcare institution carrying out a healthcare activity of treatment of children lung diseases shall be conducted during the weekend (Saturday and Sunday).

(14) The resident in outpatient pediatrics in duration of 36 months shall gain and acquire skills in emergency children medicine, intensive care and shall participate in specialist and consultative examinations in the outpatient clinic by doing a part of the residency in pediatric emergency centers, in departments for intensive care and in an outpatient clinic in duration of at least 90 days from the total duration of the residency of 36 months.

(15) The resident in outpatient pediatrics in duration of 36 months shall have the right to employ a doctor in medicine who shall be his/her replacement during the time of doing a part of the residency referred to in paragraph (14) of this Article in duration of 90 days in pediatric emergency centers, in departments for intensive care and in an outpatient clinic.

(16) The parts of the residency in outpatient pediatrics in duration of 36 months (modules) and their duration, the curricula, as well as the manner of doing the residency, and the form of the resident booklet and of the book of records of completed procedures and interventions during the residency shall be determined by the minister of health on a prior opinion of the corresponding higher education institution.

(17) After the adoption of the bylaw referred to in paragraph (16) of this Article, the Ministry of Health shall be obliged to immediately publish it on the website of the Ministry and in the "Official Gazette of the Republic of Macedonia".

(18) The minister of health shall prescribe the organizational, personnel, material and other detailed criteria, depending on the type of specialty training delivered, that should be met by the healthcare institutions and the healthcare institutions, as well as the form and the contents of the written authorization for delivery of the theory classes, that is, the practical part of the residency.

(19) 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 (18) of this Article, determine the healthcare institutions where the specialty and

sub-specialty training of healthcare workers and healthcare co-workers with a university degree is to be delivered, to which the minister of health shall issue a written authorization.

## Prerequisite

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### Article 141

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

(2) The healthcare workers with a university degree in the field of medicine may specialize if, in addition to the requirements referred to in paragraph (1) of this Article, have also at least six months of work in accordance with the acquired license for work in the primary health protection in a medical center, in accordance with the program of the Ministry of Health.

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

(4) The healthcare workers with a university degree who hold a license for work as specialists in internal and surgery branches of specialty may enroll in sub-specialty training if they have a year of work experience as specialists after the passing of the specialty examination.

## Mentor

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### Article 142

(1) The implementation of the specialty and sub-specialty training curriculum 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 specialty, that is, sub-specialty.

(2) During the implementation of the specialty and sub-specialty training curriculum, 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 specialty, that is, sub-specialty training curriculum, and the resident to succeed in acquiring the knowledge and skills during the specialty, that is, sub-specialty.

(3) The mentor shall have the role of a guide of the resident in carrying out the specialty, that is, the sub-specialty training, 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 specialty, that is, sub-specialty training curriculum, 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

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### Article 143

(1) The mentor referred to in Article 142 of this Law shall confirm the successfully acquired part of the specialty and sub-specialty training (module), which gives the resident an opportunity to continue with the specialty, that is, sub-specialty training in accordance with the curriculum.

(2) If the resident does not successfully acquire the part of the specialty, that is, sub-specialty training (the module), the duration of the specialty training shall be expanded for the time necessary to acquire the appropriate part of the specialty, that is, sub-specialty (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 curriculum.

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

## Educator

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### Article 144

(1) The residents shall acquire and achieve particular skills under the specialty, that is, sub-specialty training curriculum 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 specialty, that is, sub-specialty.

(2) The residents may provide, that is, carry out particular works in the provision of health protection in the area of specialty, that is, sub-specialty 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 residency, that is, sub-residency for which he/she has been appointed, and shall confirm the acquisition and achievement of particular skills under the specialty, that is, sub-specialty training curriculum.

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

## Delivery, interruption, and completion of the residency

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### Article 144-a

(1) The specialty training curriculum shall be implemented continuously, and the residency shall be completed following the successful termination of all of the modules according to the established curriculum and the implementation of all the procedures and interventions during the residency.

(2) In the event of absence due to illness and/or injury, the residency shall be interrupted for a period of 12 months at the most and it shall be resumed after the termination of the absence for the same period as the duration of the interruption.

(3) As an exception to paragraph (2) of this Article, in the event of prevention to work due to pregnancy, childbirth and maternity, the residency shall be interrupted for a period of 24 months at the most and it shall be resumed after the termination of the absence for the same period as the duration of the interruption.

(4) The implementation of the residency curriculum shall be entered in the resident booklet, in which the accurate and complete data, in particular regarding the commencement and termination of the residency, the duration of the module, the implemented procedures planned by the corresponding part of the specialty training, the competences acquired, that is, the skills defined by the curriculum for the corresponding module, the presence of the resident at the theory classes under the curriculum, the possible interruption of the

residency, and the opinion of the mentor regarding the time spent as a resident and regarding the meeting of the requirements for taking the intermediate examination and the specialty examination, shall also be entered.

(5) The procedures and interventions completed during the residency, for each specialty training separately, shall be entered in the course of the residency in the book of records of the completed procedures and interventions, in which accurate and complete data regarding the module title, type of the procedure, that is, intervention, date and the healthcare institution in which the procedure, that is, intervention has been made, as well as whether it has been performed independently or under supervision, shall also be entered.

(6) The procedures and interventions completed in the course of the residency, entered in the book of records referred to in paragraph (5) of this Article should correspond entirely to the contents of the residency set out in the specialty training curricula for the healthcare workers, that is, health co-workers with a university degree.

(7) Requirement for taking the intermediate and specialty examination shall be a correctly and completely filled resident booklet referred to in paragraph (4) of this Article with correct and complete data and a correctly and completely filled book of records of the completed procedures and interventions referred to in paragraph (5) of this Article with accurate and complete data, in which accurate and complete data are entered.

(8) The mentor, the educator, and the director of the healthcare institution in which the module is delivered shall, with his/her signature and seal, verify that the resident booklet referred to in paragraph (4) of this Article and the book of records of the completed procedures and interventions referred to in paragraph (5) of this Article are correctly and completely filled, that accurate and complete data are entered, and that the residency curriculum is implemented, that is, that the procedures and interventions completed during the residency correspond completely to the contents of the residency set out in the specialty training curricula for the healthcare workers and healthcare co-workers with a university degree.

## Taking the preliminary examination

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### Article 144-b

(1) The modules that last more than two months shall be completed by taking a preliminary examination. The preliminary examination shall be taken no later than a month after the completion of the module and the resident shall be obliged to pass it no later than the completion of the next module. Provided that the resident fails to pass the preliminary examination in the course of the following module, he/she shall not have the right to get enrolled at the next module.

(2) The resident shall take the preliminary examination before a commission, established by the higher education institution where the specialty training is delivered, composed of three doctors of medical science and specialists from the same or related branch of medicine for which the module is delivered, elected in academic and scientific, or scientific title.

(3) The resident taking the preliminary examination shall be obliged to use professional literature which is used at the 100 world's top higher education institutions in the field of medicine, ranked at the last list published by the Center for World - Class Universities at Shanghai Jiao Tong University and shall have the right to use also additional professional literature given as recommended not mandatory literature for the respective branch of specialty training.

(4) The preliminary examination referred to in paragraph (1) of this Article shall consist of the following three parts:

- first part, which is taken in a written form and by which the theoretical knowledge of the candidates acquired in the course of the module is checked,
- second part, which is taken in an oral form and by which the theoretical knowledge of the candidates acquired in the course of the module is checked, and
- practical part, by which the ability of the resident to apply the knowledge gained in the course of the module into practice is checked.

(5) The first part of the preliminary 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, computer-generated, the contents of which, by means of random choice, is determined by the software from the question database, by choosing one correct answer out of the five options offered, one of which is correct, two are similar, and two are incorrect, and by doing case studies, randomly chosen by the software from the case studies database. The questions shall be classified into three different groups of questions according to their difficulty, and the correct answers of all of the questions shall be marked with 45 points at the most. The first group of questions shall be composed of 30 questions, out of which each question which is answered correctly shall be marked with 0.5 points. The second group of questions shall be composed of 15 questions, out of which each question which is answered correctly shall be marked with one point. The third group of questions shall be composed of five case studies, out of which each case which is solved correctly shall be marked with three points. The taking of the first part of the preliminary examination shall last for 90 minutes. 10 The resident shall pass the first part of the preliminary examination if he/she wins at least 29 point, out of which 9 points, at the least, from the third group of questions.

(6) The second part of the preliminary examination shall be taken, as a rule, the day following the successful passing of the first part, and no later than three days as of the day the first part of the preliminary examination has been held when the resident successfully

passed the first part. The taking of the second part of the preliminary examination shall be done by giving oral answers to 10 computer awarded questions given to the resident, by means of random choice, by the software from the question and case studies database, right before the beginning of this part of the preliminary examination. Each correctly answered question shall be marked with 5.5 points, and the correct answers to all of the questions asked shall be marked with 55 points at the most. It shall be considered that the resident has passed the second part of the preliminary examination if he/she scores 38.5 points at the least.

(7) The practical part of the preliminary examination shall be taken, as a rule, the day following, and no later than three days as of, the day the second part of the preliminary exam has been held. The taking of the practical part of the preliminary examination is to check the knowledge of the professional instructions for evidence-based medicine from the field for which the module is delivered, by three cases of real patients chosen on the day the third part of the preliminary examination is taken, and the resident needs to get familiarized with the case within a period of 45 minutes, to make an anamnesis, to perform a physical examination, and to prepare a plan for the diagnostic procedures and a suitable treatment which he/she is to present before the examination commission. The taking of the preliminary examination shall be assessed with "passed" and "failed" by the commission referred to in paragraph (2) of this Article.

(8) The question database for the first part of the preliminary examination and the case study database for the second part of the preliminary examination shall be prepared by the commission referred to in paragraph (2) of this Article and it shall include 400 questions at the least, which are from the professional literature used at the 100 world's top higher education institutions in the field of medicinal sciences, ranked at the last list published by the Center for World-Class Universities at Shanghai Jiao Tong University, as well as at least 100 case studies. The database of questions and case studies which does not contain the answers to the questions, that is, the solutions of the case studies, shall be available to the residents taking the preliminary examination.

(9) The first and the second part of the preliminary examination shall be held in the premises for holding the intermediate examination and the specialty examination, specially equipped for holding the examination with material, technical, and IT equipment, internet connection, and equipment for recording the course of the examination. The taking of the first and the second part of the preliminary 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. The taking of the practical part of the preliminary examination shall not be recorded and it shall be held at an outpatient clinic, a hospital room, or at premises for interventions.

(10) During the first part of the preliminary examination only the president, the members,



and the secretary of the commission referred to in paragraph (2) of this Article may be present at the premises for holding the intermediate examination and the specialty examination, and the second part of the preliminary examination shall be public.

## Period for professional development and the rights and obligations of the resident during the residency

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### Article 144-c

(1) During the first and second year of the specialty training, the resident shall spend eight hours a day in the healthcare institution in which, under the specialty training curriculum, the general parts of the residency are delivered (hereinafter: period for professional development in a healthcare institution in which the general module is delivered), for the purpose of gaining practical professional knowledge and scientific findings.

(2) In the course of the period referred to in paragraph (1) of this Article, the resident shall, once a week, that is, four times in the course of each month, spend time on professional development during on-duty work, by which a continuous 24-hour healthcare activity in the healthcare institution in which the general module is delivered, is provided.

(3) In the case referred to in paragraph (2) of this Article, the resident shall be entitled to a 24-hour rest in the course of the next day following the day of on-duty work if he/she, in the course of a working day, spends time on professional development during on-duty work.

(4) The resident shall, starting from the third year of specialty training until the completion of the residency, spend eight hours a day in the healthcare institution in which, under the specialty training curriculum, the special parts of the residency are delivered (hereinafter: period for professional development in a healthcare institution in which the special module is delivered), for the purpose of gaining practical professional knowledge and scientific findings.

(5) In the course of the period referred to in paragraph (4) of this Article, the resident shall, once every week, that is, four times during each month, spend time on professional development during on-duty, by which a continuous 24-hour healthcare activity in the healthcare institution in which the special module is delivered is provided.

(6) In the case referred to in paragraph (5) of this Article, the resident shall be entitled to a 24-hour rest in the course of the next day following the day of on-duty work if he/she, in the course of a working day, spends time on professional development during on-duty work.

(7) When determining the total period for professional development that the resident spends in the healthcare institution in which the general module, that is, the special module is delivered in the course of a week, pursuant to paragraphs (1), (2), and (3) of this Article, that is, pursuant to paragraphs (4), (5), and (6) of this Article, the obligations of spending

eight hours a day in the healthcare institution and of spending time for professional development during on-duty work by which a continuous 24-hour healthcare activity is provided, as well as the right to a 24-hour rest when he/she spends time for professional development during on-duty work in the course of a working day, shall be taken into account.

(8) The resident shall be entitled to an annual leave in the duration of 22 working days.

(9) All the rights and obligations pursuant to the Law on Labor Relations regarding the right to a break, leaves, sick leave, and disciplinary and material liability, shall apply to the resident, unless otherwise regulated by this Law.

(10) The resident shall be obliged to wear a tag in the form of a card in a visible place containing a photo of the resident and data on his/her name, his/her status of a resident, and the branch of medicine in which he/she specializes.

(11) The resident shall be obliged to record his/her presence via the system for records of the working hours in the healthcare institution in which the module is delivered, in accordance with the schedule for professional development. Provided that the resident fails to record his/her presence, he/she shall be held disciplinary liable for violation of the working discipline as a disciplinary offense.

(12) The resident shall enjoy, that is, exercise the rights and obligations pursuant to the Law on Labor Relations in the healthcare institution from which he/she is sent to specialty training.

(13) The rights and obligations of the resident during his/her residency referred to in this Law and the tasks that the resident performs under the specialty training curriculum shall be regarded as his/her tasks and duties for the carrying out, performance, or non-performance of which he/she shall be personally and disciplinary liable.

(14) If the resident is a healthcare worker, that is, a healthcare co-worker employed in a healthcare institution, the provisions on personal and disciplinary liability referred to in Articles from 180 to 193 of this Law shall apply accordingly to the establishment of personal and disciplinary liability referred to in paragraph (13) of this Law. In this case, the disciplinary measure for the disciplinary irregularity shall be imposed by the management body of the public healthcare institution which has sent him/her to specialty training, and upon a prior written report from his/her mentor, co-mentor, or educator who, in the course of the specialty training, are considered as his/her immediate superior healthcare workers, that is, healthcare co-workers, and the management body of the healthcare institution which has sent him/her to specialty training shall establish the commission for conducting a

disciplinary procedure for a disciplinary irregularity and shall adopt the decision on imposing a disciplinary procedure for a disciplinary irregularity upon a written report from his/her mentor, co-mentor, or educator.

(15) The personal and disciplinary liability of the resident, which is identical to the personal and disciplinary liability of the resident employed in a public healthcare institution, shall be determined in the contract that the higher education institution, in which the specialty training is delivered, concludes with the resident who is a healthcare worker, that is, a healthcare co-worker employed in a private healthcare institution, another legal entity, or who is unemployed. This contract shall determine in particular that a public reprimand, 20% increase of the amount of the fee for specialty training paid for a semester during a period of one to six semesters for a disciplinary irregularity, and 30% increase for a disciplinary offense, as well as termination of the specialty training, may be imposed, by a decision, as a disciplinary measure for violation of the working discipline as a disciplinary irregularity and a disciplinary offense. A public reprimand or 20% increase of the amount of the annual fee for specialty training may be imposed for a disciplinary irregularity. If the violation of the working discipline repeats, a disciplinary measure, 30% increase of the amount of the annual fee for specialty training or termination of the specialty training, for a disciplinary offense shall be imposed. In this case, the disciplinary measure for a disciplinary irregularity shall be imposed by the management body of the public healthcare institution where the module is delivered and in which the disciplinary irregularity has been made, upon a prior written report from his/her mentor, co-mentor, or educator. The management body of the public healthcare institution where the module is delivered and in which the disciplinary irregularity has been made shall establish the commission for conducting a disciplinary procedure for a disciplinary offense and shall adopt the decision on imposing a disciplinary procedure for a disciplinary irregularity, upon a written report from his/her mentor, co-mentor, or educator.

## Participation of the residents in the morning and daily meeting

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### Article 144-d

(1) Every morning, during the overall duration of the residency, the medical director of the public healthcare institution in which the special module is delivered shall, along with one doctor of medicine, a specialist with at least 7 years of work experience as a specialist, convene a meeting with all residents. The educator shall participate in the morning meeting, and the mentor of the resident shall participate when the resident reports of the cases he/she has had during the previous day.

(2) At the morning meeting, the resident shall report on the cases he/she had the previous day according to the referral diagnoses and shall, publicly, before everyone present, suggest which examinations are needed for confirming that referral diagnosis, how the examination should be, and shall present the instruction for evidence-based medicine for that diagnosis.

(3) During the overall duration of the residency, the medical director of the public healthcare institution in which the general module is delivered shall, in the course of the day, along with one doctor of medicine, a specialist with at least seven years of work experience as a specialist, convene a daily meeting with all residents. The educator shall participate in the daily meeting, and the mentor of the resident shall participate when the resident reports of the cases he/she has during the previous day.

(4) At the daily meeting, the resident shall report on the cases he/she had the previous day according to the referral diagnoses and shall, publicly, before everyone present, suggest which examinations are needed for confirming that referral diagnosis, how the examination should be, and shall present the instruction for evidence-based medicine for that diagnosis.

(5) The medical doctor of the public healthcare institution referred to in paragraphs (1) and (3) of this Article shall prepare a list of all the specialists with at least seven years of work experience as specialists, who shall, on rotational basis, participate in the morning and daily meetings.

## Mandatory training for the residents

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### Article 144-e

(1) In the course of the overall duration of the specialty training, the resident shall attend training for using the integrated health information system, training for the rulebook for hospital culture, and training for rational use of medicines and resources in duration of at least 250 hours in total for all the types of training, that is, 150 hours for the residents whose residency lasts for two, that is, four years.

(2) The participation of the residents in the training referred to in paragraph (1) of this Article shall constitute a condition for continuing in the next year of specialty training.

(3) The schedule of the mandatory training referred to in paragraph (1) of this Article shall be determined by the Ministry of Health, upon a proposal of the higher education institution in which the specialty training is delivered.

(4) The mandatory training referred to in paragraph (1) of this Article shall be conducted by trainers authorized by the Ministry of Health.

## Learning foreign languages

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### Article 144-f

(1) The resident shall mandatorily have knowledge of at least two world languages, one of which shall mandatorily be the English language and the second language shall be one of the following world languages: German, French, Italian, Turkish, Chinese, Spanish, or Russian.

(2) The resident shall have knowledge of the English language at B2 level at least according to the European language portfolio (Common European Framework of Reference for Languages: Learning, Teaching, Assessment), and the other language at A2 level according to the European language portfolio (Common European Framework of Reference for Languages: Learning, Teaching, Assessment), certified by an official European tester, a member of ALTE (Association of Language Testers in Europe).

(3) For the purpose of achieving the level of knowledge of the foreign languages referred to in paragraph (2) of this Article, the resident shall learn the foreign languages in the course of the overall duration of the specialty training, that is, 180 minutes in total per week shall be spent learning the English language, which can be arranged in at least three lessons in duration of 60 minutes each, and 120 minutes in total per week shall be spent learning the second foreign language, which can be arranged in at least two lessons in duration of 60 minutes each.

(4) As an exception to paragraph (3) of this Article, the resident holding an internationally recognized certificate issued by an official European tester, a member of ALTE (Association of Language Testers in Europe), or a certificate from an international institution verifying his/her knowledge of the English language at B2 level, or A2 level for the second foreign language, shall not have to attend lessons. The resident shall be obliged to submit the internationally recognized certificate, that is, the certificate from an international institution proving his/her knowledge of the foreign languages at the required level to the higher education institution in which the specialty training is delivered.

(5) The resident who has completed the first, second, or third cycle of studies in the field of medical science in English or in one of the other languages referred to in paragraph (1) of this Article at one of the 200 top ranked universities on the Shanghai Ranking - ARWU (Academic Ranking of World Universities) and for which he/she possesses a verified diploma, shall not have to attend lessons pursuant to paragraph (2) of this Article for the foreign language in which he/she has completed the studies, but he/she shall have to attend lessons for the other foreign language. He/she shall be obliged to deliver to the higher education institution in which the specialty training is delivered a certificate or a verified diploma for a completed first, second, or third cycle of studies at one of the 200 top ranked universities on the Shanghai Ranking - ARWU (Academic Ranking of World Universities) proving his/her knowledge of the foreign language in which he/she has completed the studies at the required level.

(6) The foreign languages shall be learned after the termination of the period for professional development of the resident and the lessons for learning foreign languages cannot be held during the period of professional development of the resident.

(7) When learning the foreign languages particular attention shall be paid to learning the foreign language medical terminology.

(8) The higher education institution in which the specialty training is delivered shall be obliged to provide the residents to study the English language in cooperation with the higher education institutions in the field of philology or in cooperation with other institutions in the field of education where the teaching shall be delivered by persons who have at least 10 years of experience in the profession, and the Ministry of Health shall be obliged to organize the learning of the foreign languages which, pursuant to paragraph (1) of this Article, are learnt as a second language. The higher education institution in which the specialty training is delivered shall be obliged to conclude a contract with the higher education institutions in the field of philology sciences for testing the residents' knowledge of the two foreign languages at the level referred to in paragraph (2) of this Article. The Ministry of Health shall compensate the costs for the testing of residents' knowledge of the second foreign language at the level referred to in paragraph (2) of this Article with the higher education institutions in the field of philology sciences.

(9) The costs for studying the English language and the other foreign language and for testing the residents, pursuant to paragraph (8) of this Article, shall be included in the costs for delivery of the specialty training.

## Use of professional literature

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### Article 144-g

(1) During the specialty, that is, sub-specialty training, the resident shall mandatorily use professional literature from the 100 world's top universities according to the rank list of: Shanghai Ranking - ARWU (Academic Ranking of World Universities);. 11

(2) The professional literature referred to in paragraph (1) of this Article shall be literature out of which the questions for taking the preliminary examinations, the specialty and intermediate examination are prepared, as well as literature out of which lecturers for the theory classes referred to in Article 144-h paragraph (2) of this Law. are prepared and delivered. 12

(3) During the specialty, that is, sub-specialty training, the resident may also use additional professional literature for each specialty separately, as recommended not mandatory professional literature for the respective branch of specialty training.

(4) The list of compulsory professional literature and authors referred to in paragraph (1) of this Article and the recommended not mandatory professional literature referred to in paragraph (3) of this Article shall be set out by the Government of the Republic of Macedonia, upon a proposal of the Ministry of Health, for each specialty separately.

## Obligations of the resident in the course of the overall duration of the residency

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## Article 144-h

(1) In the course of each year of residency, the resident shall be obliged to acquire the envisaged skills by performing procedures, interventions, by assisting, and by performing surgeries, within the type and scope established by the specialty curriculum.

(2) In the course of the overall duration of the residency, the residents of all of the specialty branches shall have at least 250 hours of theory classes in total from the corresponding specialty branch, out of which at least 15% of the total number of hours from the envisaged theory classes shall be in the field of scientific-research work, adopting a clinical decision, communication skills, public health, ability of acquiring and transferring knowledge, ethics, and regulations and promotion of the health.

(3) The lectures in the corresponding branch of specialty shall be organized and delivered by the higher education institution in which the specialty training is delivered.

## Obligations of the resident in the first and second year of residency

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### Article 144-i

(1) In the course of the first and second year of residency, the resident shall mandatorily acquire practical skills through training, organized by the Medical Simulation Center, on equipment which simulates pathological states of a person and which checks the acquired skills through diagnostic and therapeutic interventions performed on the equipment, at actual cases chosen randomly, and where the entire course of the intervention shall be video recorded.

(2) The training referred to in paragraph (1) of this Article shall last at least an hour during each month of the year, that is, at least 11 hours in the course of the year in total.

(3) The Medical Simulation Center shall provide simulation of at least 40 life-threatening, that is, urgent states with different vital parameters.

(4) The video recording of the entire course of the intervention performed by the resident shall be kept for at least five years after the termination of the residency.

(5) In the course of the first year of residency, the resident shall be obliged to successfully acquire the techniques of taking blood, giving infusion, giving injection, performing surgical dressing, and measuring the vital parameters.

## Intermediate examination

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### Article 144-j

(1) Following the completion of the second year of residency, the resident shall take an intermediate examination which shall be organized for each medical branch in which the resident specializes separately. Condition for commencing the third year of residency shall be the successful passing of this examination.

(2) The intermediate examination shall be taken before a commission established by the minister of health, upon the proposal of the higher education institution in which the specialty training delivered, composed of three doctors of medical science, specialists from the same or related branch of medicine for which the specialty training is delivered, elected in academic and scientific, or scientific title, who have published at least five impact factor scientific papers and who have spent at least three months of training in the course of the last five years in the OECD member countries. The members of the commission shall have deputies who meet the same requirements as the members of the commission. 13

(3) As an exception to paragraph (2) of this Article, the case when a commission of members who meet the requirements referred to in paragraph (2) of this Article cannot be formed, the intermediate examination shall be taken before a commission formed by the minister of health, on a proposal of the higher education institution where the specialty training is delivered, composed of three members who are specialists in the same or related branch of medicine for which specialty training is delivered, elected in a title part-time or full-time professor. Deputies shall be designated for the members of the commission who meet the same requirements as the members of the commission. 14

(4) The resident taking the intermediate examination shall be obliged to use professional literature which is used at the 100 world's top higher education institutions in the field of medical sciences, ranked at the last list published by the Center for World-Class Universities at Shanghai Jiao Tong University.

(5) The intermediate examination shall consist of the following three parts:

- first part, which is taken in a written form and by which the theoretical knowledge of the candidates acquired in the course of the module is checked,
- second part, which is taken in an oral form and by which the theoretical knowledge of the candidates acquired in the course of the module is checked, and
- practical part, by which the ability of the resident to apply the knowledge gained in the course of the module into practice is checked.

(6) The first part of the intermediate 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, computer-generated, the contents of which is determined, by means of random choice, by the software from the question database, by choosing one correct answer out of the five options offered, one of which is correct, two are similar, and two are incorrect, and by doing case studies, randomly chosen by the software from the case studies database. The questions shall be classified into three different groups of questions according to their



difficulty, and the correct answers of all of the questions shall be marked with 45 points at the most. The first group of questions shall include 30 questions, out of which each question which is answered correctly shall be marked with 0.5 points. The second group of questions shall include 15 questions, out of which each question which is answered correctly shall be marked with one point. The third group of questions shall include five case studies, out of which each case which is solved correctly shall be marked with three points. The taking of the first part of the intermediate examination shall last 90 minutes. The resident shall pass the first part of the intermediate examination if he/she wins at least 29 points, out of which at least 9 points from the third group of questions.

(7) The second part of the intermediate examination shall be taken, as a rule, the day following the successful passing of the first part, and no later than three days as of the day the first part of the intermediate examination has been held when the resident successfully has passed the first part. The taking of the second part of the intermediate examination shall be done by giving oral answers to 10 computer awarded questions given to the resident, by means of random choice, by the software from the question and case studies database, right before the beginning of this part of the intermediate examination. Each correctly answered question shall be marked with 5.5 points, and the correct answers to all of the questions asked shall be marked with 55 points at the most. It shall be considered that the resident has passed the intermediate examination if the resident wins 38.5 points at the least.

(8) The practical part of the intermediate examination shall be taken, as a rule, the day following the successful passing of the second part, and no later than five days as of the day the second part of the intermediate examination has been held when the resident successfully has passed the second part. The taking of the practical part of the intermediate examination is to check the knowledge of the professional instructions for evidence-based medicine, by means of three cases of real patients chosen on the day the third part of the intermediate examination is taken, and the resident needs to get familiarized with the case within a period of 45 minutes, to make an anamnesis, to perform a physical examination, and to prepare a plan for the diagnostic procedures, and a suitable treatment which he/she is to present before the examination commission. The taking of the intermediate examination shall be assessed with "passed" and "failed" by the commission referred to in paragraph (2) of this Article.

(9) The question database for the first and the second part of the intermediate examination shall include at least 800 questions for each branch of medicine for which specialty training is delivered, which are from the professional literature used at the 10 world's top higher education institutions in the field of medicine, ranked at the last list published by the Center for World-Class Universities at Shanghai Jiao Tong University, as well as at least 200 case studies for each branch of medicine for which specialty training is delivered.

(10) The first and the second part of the intermediate examination shall be held in the

premises for holding the intermediate examination and the specialty examination, specially equipped for holding the examination with material, technical, and IT equipment, internet connection, and equipment for recording the course of the examination. The taking of the first and the second part of the intermediate 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. The taking of the practical part of the intermediate examination shall not be recorded, and it shall be held at an outpatient clinic, hospital room, or at premises for performing interventions.

(11) During the first part of the intermediate examination only the president, the members, and the secretary of the examination commission may be present at the premises for holding the intermediate examination and the specialty examination, and the second part of the intermediate examination shall be public.

(12) The public shall be informed about the date and time of holding the first and the second part of the intermediate examination, at least 24 hours prior to the holding of the examination.

(13) After passing the intermediate examination, the resident shall obtain the status of a senior resident.

## National Commission for Preparation of the Questions and Case Studies Databases for Taking the Intermediate and Specialty Examination

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### Article 144-k

(1) The database of questions and the database of case studies for the intermediate and the specialty examination shall be prepared by the National Commission for Preparation of the Questions and Case Studies Databases for Taking the Intermediate and Specialty Examination (hereinafter: the National Commission).

(2) The minister of health shall establish the National Commission which shall consist of ten members who meet the requirements referred to in Article 144-j paragraph (2) of this Law, out of whom three members shall be proposed by the higher education institution which delivers the specialty training. All of the members of the Macedonian Academy of Sciences and Arts in the field of medical science and one representative from the Doctors', Dental, that is, Pharmaceutical Chamber, depending on the specialty for which the intermediate, that is, specialty examination is taken, shall also participate in the work of the National Commission as its members. 15

(3) The National Commission shall prepare the questions and the case studies for the first and the second part of the intermediate, that is, specialty examination by using the professional literature which is used at the ten world's top higher education institutions in

the field of medicine, ranked at the last list published by the Center for World-Class Universities at Shanghai Jiao Tong University.

(4) The National Commission shall review and update the questions and case studies databases for the intermediate and the specialty examination at least once in a period of two years.

(5) During the review, the Commission shall particularly take into account the changes of the professional instructions for the evidence-based medicine for particular specialties on which the question, that is, the case study is based, the number of residents that answered it, the success in answering them, as well as the other criteria that may affect the quality improvement of the questions and case studies databases.

(6) The National Commission shall decide whether the questions and the case studies shall be altered or completely removed from the questions and case studies databases, based on the completed review and update of the questions and case studies databases.

(7) The members of the National Commission shall be entitled to remuneration for preparing the database of questions and database of case studies for the intermediate and specialty examination, and the minister of health shall adopt a decision thereof.

(8) The remuneration referred to in paragraph (7) of this Article shall be in the amount of an average salary in the Republic of Macedonia paid in the previous year, published by the State Statistical Office of the Republic of Macedonia.

## Spatial conditions and material-technical and IT equipment for holding the intermediate and specialty examination

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### Article 144-I

(1) The higher education institution where the specialty training is delivered shall technically carry out the intermediate, that is, specialty examination and shall conduct the professional and administrative-technical activities required for carrying out the intermediate, that is, the specialty examination.

(2) The higher education institution in which the specialty training is delivered shall have at its disposal at least one facility for holding the examination, specially equipped for holding a professional examination with material-technical and IT equipment, internet connection, and equipment for recording the examination.

(3) The Ministry of Health and the State Sanitary and Health Inspectorate shall check whether the facility, that is, facilities for holding the examination are equipped pursuant to paragraph (2) of this Article and whether the equipment is operational, and if some irregularities are established, they shall impose a temporary measure prohibiting the holding of the examination which shall last until the elimination of the irregularities.

(4) The criteria pertaining to the spatial conditions and the material-technical and IT equipment of the premises for holding the intermediate and specialty examination, as well as the preliminary examinations, shall be determined by the minister of health.

(5) After the adoption of the bylaw referred to in paragraph (4) of this Article, the Ministry of Health shall be obliged to publish it on the website of the Ministry and in the "Official Gazette of the Republic of Macedonia".

Practical training in a general hospital or a specialized hospital, in an emergency medical care service or a medical center, doing daily visiting round and attendance, that is, participation in the performance of an autopsy

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#### Article 144-m

(1) During the third year of residency, the senior resident shall be obliged to examine patients who need to have a control check-up under the supervision of the educator, and after the completion of the third year of residency, the senior resident shall be obliged to examine patients who need to have a control check-up independently, without the supervision of the educator, and patients who have been referred to specialist and consultative examination for the first time under the supervision of the educator.

(2) During the third year of residency, the senior resident shall attend a module in the duration of at least two months at a general or a specialized hospital in the Republic of Macedonia.

(3) The schedule of the senior residents in the general and specialized hospitals shall be made by the Ministry of Health, on a mutual proposal from the higher education institution in which the specialty training is delivered and the authorized healthcare institution in which the special part of the residency of the resident is spent.

(4) The senior resident, for the period spent in a general or a specialized hospital, shall be entitled to compensation of the travel costs in the amount of a bus or railway ticket which shall be born by the healthcare institution which sends him/her to specialty training.

(5) In the course of the third year of residency, the senior resident shall mandatorily perform at least one daily visiting round per day in the healthcare institution in which the module is delivered, which cannot be at the same time as the regular visiting round of the residents, and which shall be perform individually, and not in a group with other residents.

(6) When performing the daily visiting round, the senior resident shall be obliged to visit every hospitalized patient in the healthcare institution in which the module is delivered, to get familiarized with his/her health condition, to ask the patient about his/her health

condition, if contactable, to check whether he/she has taken the prescribed therapy, and whether he/she has an adverse reaction to the therapy.

(7) The senior resident shall keep a resident logbook of the daily visiting rounds (hereinafter: the resident logbook), in which he/she shall, when performing the daily visiting round, enter data about each patient individually, and shall particularly enter data about the established diagnosis by checking every element of the procedure pursuant to the instructions for evidence-based medicine and by comparing the activities taken by the residents treating the patient.

(8) If, in the course of the daily visiting round, the senior resident establishes that the patient is not treated in line with the instructions for evidence-based medicine, he/she shall be obliged to, immediately, without any delay, inform the specialist treating the patient and the mentor, and if they fail to take appropriate measures, he/she shall also notify the director of the healthcare institution in which the module is delivered.

(9) The director of the healthcare institution in which the module is delivered shall be obliged to take appropriate measures in the case referred to in paragraph (8) of this Article if the senior resident has delivered a notification to the director that a particular patient is not being treated in line with the instructions for evidence-based medicine.

(10) The director of the public healthcare institution shall determine the time schedule of the daily visiting rounds for each senior resident separately and it shall be published publicly.

(11) Condition for taking the specialty examination shall be a correctly and completely filled resident logbook.

(12) The mentor, the educator, and the director of the healthcare institution in which the respective module of the specialty training is delivered shall, with his/her signature and seal, verify that the resident logbook is correctly and completely filled and that the daily visiting rounds have been carried out.

(13) In the course of the last and the penultimate year of residency, the senior resident shall attend at least five autopsies per year, individually or in a group with other residents, depending on the number of autopsies available, except for the resident in a particular branch of surgery who, starting from the first year of specialty training as a member of the team that performs the autopsy, participates in the performance of at least five autopsies per year for the purpose of gaining practical knowledge in the field of anatomy and research and study of the structure of the organism by means of dissection.

(14) In the course of the last year of the residency, the senior resident shall mandatorily attend modules where he/she shall be actively included in the work plan of the:

- emergency medical care service, for a period of at least a month;

- hospital or medical center with a head office in the municipality in which the head office of the public healthcare institution which sent the healthcare worker or the healthcare co-worker to specialty training is located, for a period of at least three months;
- emergency center or clinical hospital, for a period of at least 15 working days.

(15) The time schedule of the modules referred to in paragraph (14) of this Article shall be determined by the Ministry of Health, on a proposal of the higher education institution in which the specialty, that is, sub-specialty training is delivered.

(16) The form and contents of the resident logbook of the daily visiting rounds and the manner of filling it shall be determined by the minister of health, on a proposal of the higher education institution in the field of medical sciences in which the specialty training is delivered.

(17) Following the adoption of the bylaw referred to in paragraph (16) of this Law, the Ministry of Health shall be obliged to publish it immediately on the website of the Ministry and in the "Official Gazette of the Republic of Macedonia".

## Temporary license for work as a senior resident and a seal of a senior resident

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### Article 144-n

(1) Following the completion of the third year of the residency, the senior resident shall obtain a temporary license for work as a senior resident in the field of medicine in which he/she specializes, and which he/she shall use until the termination of the residency pursuant to the specialty training curriculum.

(2) The temporary license for work as a senior resident shall be issued by the Doctors' Chamber of Macedonia upon the request of the resident, who shall submit the request for issuance of a temporary license the day after the completion of the third year of residency, and shall attach the following to the request:

- 1) a diploma for completed appropriate education in the field of medicine;
- 2) a proof of a passed professional examination;
- 3) a proof of a passed intermediate examination, and
- 4) a proof of completed three years of residency.

(3) The Doctors' Chamber of Macedonia shall be obliged to issue the temporary license for work as a senior resident within a period of seven days as of the day of receipt of the resident's request referred to in paragraph (2) of this Article.

(4) The minister of health shall issue an approval for making and using a temporary seal of the senior resident referred to in paragraph (1) of this Article, which he/she shall use when performing the examinations, procedures, and interventions in the healthcare institutions

in which the modules are delivered.

(5) The temporary seal referred to in paragraph (4) of this Article can be used until the completion of the residency pursuant to the specialty training curriculum in the public healthcare institutions in which the modules are delivered until the taking of the specialty examination, without the possibility of re-issuance of an approval.

(6) It shall be stated in the approval referred to in paragraph (4) of this Article that it is issued to a senior resident on the basis of this Law.

(7) The examinations and interventions performed by the senior resident referred to in paragraph (1) of this Law shall be scheduled via the electronic list of scheduled examinations and interventions.

## Specialty training in surgery and internal medicine

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### Article 144-o

(1) In the course of the first semester of the first year of specialty training in surgery, that is, internal medicine, the resident shall be obliged to successfully perform at least three interventions on simulated life-threatening states on a simulator at the Medical Simulation Center, and the entire course of the intervention shall be video recorded.

(2) The Medical Simulation Center shall issue a certificate to the surgery resident if he/she successfully performs at least three surgical interventions on a simulator pursuant to paragraph (1) of this Article.

(3) If the resident fails to successfully perform at least three surgical interventions on a simulator pursuant to paragraph (1) of this Article, the Medical Simulation Center shall not issue a certificate to the resident and the duration of the specialty training shall be extended for the period he/she needs in order to successfully perform at least three surgical interventions on a simulator.

(4) The resident specializing in surgery shall assist and perform surgical interventions pursuant to the curriculum for specialty training in surgery, when he/she performs works as an assistant in surgical interventions and as a surgeon operator, together with his/her mentor and/or educator.

(5) The resident specializing in internal medicine shall be obliged to acquire skills of non-invasive and invasive diagnostic methods within the scope determined by the specialty training curriculum.

(6) The resident, in the last year of the specialty training in internal medicine, in the course of the delivery of the modules, shall mandatorily acquire skills of doing aspiration, fine-needle, and/or endoscopic biopsies, and he/she shall be obliged to independently conduct

at least that number of interventional diagnostic procedures as set out in the corresponding specialty training curriculum.

## Obligations of the healthcare institution for creating conditions for delivery of modules

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### Article 144-p

(1) The healthcare institution where a module is delivered shall be obliged to provide at least one facility for the needs of the residents and the sub-specialty trainees where conditions for rest and leaving personal stuff are ensured.

(2) The number of facilities referred to in paragraph (1) of this Article shall depend on the number of residents and sub-specialty trainees that do a residency, that is, sub-residency.

## Status of the private residents and sub-specialty trainees

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### Article 144-q

(1) By acquiring the status of a private resident, that is, a private sub-specialty trainee through the program for co-financing referred to in Articles 150-d and 150-e of this Law, the healthcare worker and the healthcare co-worker enrolled for specialty, that is, sub-specialty training in accordance with Article 150 of this Law (a private resident, that is, a private sub-specialty trainee) shall be employed for a definite period of time in the public healthcare institution where he/she has applied for specialty, that is, sub-specialty training for the period of doing the residency until taking the specialty, that is, sub-specialty examination.

(2) During the employment referred to in paragraph (1) of this Article, the private resident, that is, the private sub-specialty trainee shall have the right to a salary in the amount of one average monthly salary in the Republic of Macedonia paid for the previous year and other salary compensations in accordance with the law.

(3) The healthcare institutions where the module is delivered, based on a concluded agreement with the private resident, that is, the private sub-specialty trainee referred to in paragraph (1) of this Article, for the period of duration of the module, shall pay compensation for the time spent for professional development during on-duty which provides 24-hours healthcare activity in the same amount as for the employees in the public healthcare institutions in accordance with a collective agreement.

(4) If the private resident, that is, the private sub-specialty trainee stops doing the residency, that is, the sub-residency in the course of doing the residency, that is, the sub-residency contrary to Article 144-a, paragraphs (2) and (3) of this Law, he/she shall be obliged to compensate the costs and the other compensations for his/her residency, that is, sub-residency according to the determined calculation by the Ministry of Health. The private



resident, that is, the private sub-specialty trainee shall have the same obligation if he/she does not continue the residency, that is, the sub-residency upon the expiry of the time for interruption referred to in Article 144-a paragraphs (2) and (3) of this Law.

(5) The private resident, that is, the private sub-specialty trainee shall not compensate the costs referred to in paragraph (3) of this Article if he/she has stopped the residency, that is, the sub-residency in accordance with Article 144-a paragraphs (2) and (3) of this Law, but has afterwards continued the residency, that is, the sub-residency.

## Conditions for taking the specialty examination

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### Article 145

(1) After conducting all of the procedures and interventions contained in the specialty training curriculum, the resident shall take the specialty examination.

(2) For the purpose of taking the specialty examination the resident should:

- have a resident booklet with duly completed and verified parts of the residency,
- have passed all of the preliminary examinations,
- have a written consent from the mentor, and
- have published, independently as an author or together with other authors as a co-author, at least one scientific paper in an international journal which has an international editing board composed of at least five countries, where the number of members from each country cannot exceed 40% of the total number of members, and which is published for a period of at least five years continuously.

## Taking the specialty examination

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### Article 145-a

(1) The resident shall, in the presence of his/her mentor, take the specialty examination after mastering the specialty training curriculum.

(2) The resident shall take the specialty examination referred to in paragraph (1) of this Article within a period of six months as of the day of completion of the residency at the latest, before an examination commission established by the minister of health, on a proposal of the higher education institution in which the specialty training is delivered.

(3) The examination commission referred to in paragraph (2) of this Article shall be composed of three members who are doctors of medicine, specialists in the same or a related branch of medicine for which the specialty training is delivered, elected in academic and scientific, or scientific title, who have published at least five impact factor scientific papers and who have spent at least three months of training in the course of the last five years in the OECD member countries,.. 16 The members of the commission shall have

deputies who meet the same requirements as the members of the commission. The mentor who participated in the carrying out of the residency cannot be a member of the examination commission. 17

(4) As an exception to paragraph (3) of this Article, in the case when a commission of members who meet the requirements referred to in paragraph (3) of this Article cannot be formed, the specialty examination shall be taken before a commission formed by the minister of health, on a proposal of the higher education institution where the specialty training is delivered, composed of three members who are specialists in the same or related branch of medicine for which specialty training is delivered, elected in a title part-time or full-time professor. Deputies shall be designated for the members of the commission who meet the same requirements as the members of the commission. 18

(5) The application for taking the specialty examination shall be filed within a period of at least a month prior to the taking of the examination.

(6) The higher education institution in which the specialty training is delivered shall approve the taking of the specialty examination and shall determine the date of the specialty examination.

(7) The resident taking the specialty examination shall be obliged to use professional literature which is used at the ten world's top higher education institutions in the field of medicine, ranked at the last list published by the Center for World-Class Universities at Shanghai Jiao Tong University.

(8) The specialty examination shall consist of the following three parts:

- first part, which is taken in a written form and by which the theoretical knowledge of the candidates acquired in the course of the module is checked,
- second part, which is taken in an oral form and by which the theoretical knowledge of the candidates acquired in the course of the module is checked, and
- practical part, by which the ability of the resident to apply the knowledge gained in the course of the residency into practice is checked.

(9) The first part of the specialty 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, computer-generated, the contents of which is determined, by means of random choice, by the software from the question database, by choosing one correct answer out of the five options offered, one of which is correct, two are similar, and two are incorrect, and by doing case studies, randomly chosen by the software from the case studies database. The questions shall be classified into three different groups of questions according to their difficulty, and the correct answers of all of the questions shall be marked with 45 points at the most. The first group of questions shall be composed of 30 questions, out of which each question which is answered correctly shall be awarded 0.5 points. The second group of

questions shall be composed of 15 questions, out of which each question which is answered correctly shall be awarded one point. The third group of questions shall be composed of five case studies, out of which each case which is solved correctly shall be awarded three points. The taking of the first part of the specialty examination shall last 90 minutes, out of which at least 30 minutes shall be for the third group of questions. The resident passes the first part of the specialty examination if he/she wins at least 29 points, out of which at least 9 points from the third group of questions.

(10) The second part of the specialty examination shall be taken, as a rule, the day following the successful passing of the first part and no later than three days as of the day the first part of the specialty examination has been held when the resident successfully has passed the first part. The taking of the second part of the specialty examination shall be done by giving oral answers to 10 computer awarded questions given to the resident, by means of random choice, by the software from the question and case studies database, right before the beginning of this part of the specialty examination. Each correctly answered question shall be awarded 5.5 points, and the correct answers to all of the questions asked shall be awarded 55 points at the most. The second part of the specialty examination shall be considered as passed if the resident wins at least 38.5 points.

(11) The practical part of the specialty examination shall include examination of the knowledge and skills in the Medical Simulation Center, as well as examination of the knowledge and skills with a real patient. The practical part of the specialty examination shall be taken, as a rule, the day following the successful passing of the second part and no later than five days as of the day the second part of the specialty examination has been held when the resident successfully has passed the second part. The taking of the practical part of the specialty examination with a real patient shall check the knowledge of the professional instructions for evidence-based medicine by means of three cases of real patients chosen on the day the third part of the specialty examination is taken, and the resident should be familiarized with the case within a period of 45 minutes, to make an anamnesis, to perform a physical examination, and to prepare a plan for diagnostic procedures and a suitable treatment which he/she is to present before the examination commission. The resident specializing in surgery shall be obliged to perform one surgical intervention, and the resident specializing in internal medicine shall be obliged to perform at least three interventions or other diagnostic procedures. The commission referred to in paragraph (2) of this Article shall assess the taking of the third part of the specialty examination with "passed" and "failed".

(12) The question database for the first and the second part of the specialty examination shall contain at least 1.500 questions for each branch of medicine for which specialty training is delivered, which are from the professional literature used at the 100 world's top

higher education institutions in the field of medicine, ranked at the last list published by the Center for World-Class Universities at Shanghai Jiao Tong University, as well as at least 500 case studies for each branch of medicine for which specialty training is delivered.

(13) The first and the second part of the specialty examination shall be taken in the premises for holding the intermediate and the specialty examination, specially equipped for holding the examination with material, technical, and IT equipment, internet connection, and equipment for recording the course of the examination. The holding of the first and the second part of the specialty 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. The holding of the third part of the specialty examination shall include examination of the knowledge and the skills in the Medical Simulation Center where video recording of the entire course of the intervention shall be made, as well as examination of the knowledge and the skills with a real patient in an outpatient clinic, a hospital room, or at premises for performing interventions where no recording shall be made.

(14) Only the president, the members, and the secretary of the examination commission may be present at the premises for holding the intermediate examination and the specialty examination during the first part of the specialty examination, and the second part of the intermediate examination shall be public.

(15) When taking the specialty examination, the duration of the examination shall be set out in advance and its exceeding shall mean that the examination is not passed.

#### Article 145-b

(1) Minutes in which the examination commission states whether the resident has passed or has failed the examination shall be kept for the specialty examination. The minutes shall be signed by all of the members of the commission and by the recording secretary.

(2) The resident who does not pass the first or the second, that is, the practical part of the specialty examination shall have the right to retake that part within a period of 30 days at least and 60 days at the most as of the day on which that part of the specialty examination has been taken for the first time.

(3) The resident who does not pass the examination shall have the right to retake it once more. If the resident fails to pass the specialty examination at the second attempt, he/she shall be returned to repeat the residency in the duration determined by the examination commission, which cannot be less than 90 days.

(4) If the resident does not apply for taking the specialty examination within the time period referred to in Article 145-a paragraph (2) of this Law, or if gives up from re-taking the examination that he/she started taking without any justifiable reasons, it shall be

considered that he/she has not passed the examination and he/she shall have the right to take the examination once more within the time period set out by the examination commission, which cannot be longer than 90 days as of the expiry of the time period referred to in Article 145-a paragraph (2) of this Law, that is, as of the day he/she has given up from taking the examination.

(5) If the resident fails to pass the specialty examination within a period of one year as of the day of completion of the residency, he/she shall lose the right to take the examination, except in the events of longer leave due to illness or injury, as well as prevention to work due to pregnancy, childbirth and maternity.

## Training of the resident abroad

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### Article 145-c

(1) The resident shall acquire the professional title of a specialist in the respective branch of specialty, for which the higher education institution shall issue a certificate for acquiring a professional title of a specialist, that is, sub-specialist. if he/she has: 19

- 1) a certificate for a passed specialty examination, and
- 2) a proof that the resident has attended training, in an OECD or EU member country, in the duration of three months.

(2) For the purpose of meeting the condition referred to in paragraph (1) point 2) of this Article, after passing the specialty examination, the Ministry of Health shall send the resident employed in a public healthcare institution to training abroad in an OECD or EU member country, in the duration of three months, and shall compensate the costs for the training.

(3) The resident who is enrolled in a specialty, that is, sub-specialty training in accordance with Article 150 of this Law shall cover the costs for the training carried out abroad in an OECD or EU member country, in the duration of three months, which he/she attends for the purpose of meeting the condition referred to in paragraph (1) point 2) of this Article, by his/her own funds.

(4) The resident who is enrolled in specialty training in accordance with Article 150 of this Law shall be entitled to request from the Ministry of Health to cover the costs for the training carried out abroad in an OECD or EU member country, in the duration of three months, for which he/she shall conclude a contract with the Ministry of Health regulating the mutual rights and obligations and, in particular, the obligation of the resident to work in a public or private healthcare institution in the Republic of Macedonia for a period of at least three years after acquiring the status of a specialist, as well as the amount of the funds that he/she should compensate if he/she, at his/her own request or fault, fails to meet this obligation.

(5) The amount of the funds that the resident should compensate in the event he/she fails to meet the obligation referred to in paragraph (4) of this Article cannot be less than ten times the amount of the costs for the training carried out abroad in an OECD or EU member country in the duration of three months as referred to paragraph (4) of this Article.

## Termination of specialty, that is, sub-specialty training

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### Article 145-d

(1) The specialty, that is, sub-specialty training shall terminate in the following cases:

- if the interruption in the residency lasts longer than the period referred to in Article 144-a of this Law,
- if the employment of the resident, that is, sub-specialty trainee in the healthcare institution which has sent him/her to specialty, that is, sub-specialty training has terminated,
- on request of the resident,
- if the resident, that is, sub-specialty trainee does not conduct the procedures and the interventions according to the curriculum for specialty, that is, sub-specialty training in the period of three months and he/she has not submitted a request for interruption referred to in Article 144-a paragraphs (2) and (3) of this Law to the higher education institution,
- if he/she has not passed the intermediate examination in accordance with Article 144-j of this Law, that is, has not passed the specialty examination within the deadline referred to in Article 145-a paragraph (2) of this Law, and
- in other cases set out by this or another law.

(2) The procedure for termination of the specialty, that is, sub-specialty training shall be initiated on a request of the healthcare institution in the cases of paragraph (1) line 1 and 2 of this Article, on a request of the resident in the case of paragraph (1) line 3 of this Article, as well as on a request of the mentor, that is, the co-mentor in the case of paragraph (1) lines 4, 5 and 6 of this Article. Documents proving that the requirements for termination of the specialty, that is, sub-specialty training referred to in paragraph (1) of this Article are met shall be attached to the request for termination of the specialty, that is, sub-specialty training.

(3) The higher education institution shall conduct the procedure for termination of the specialty, that is, sub-specialty training and shall adopt a decision on termination of the specialty, that is, sub-specialty training after it establishes that the requirements for termination of the specialty, that is, sub-specialty training are met.

(4) The resident who is not satisfied with the adopted decision on termination of the specialty, that is, sub-specialty training shall have the right, within a period of five days as of the day of receipt of the decision, to file an appeal with the second instance commission formed by the higher education institution.

## Revocation of the authorization of the mentor and the educator

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### Article 146

If at least two residents with the same mentor, that is, educator have failed to successfully acquire the particular skills under the specialties, that is, sub-specialties training curriculum 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.

## Termination of the authorization of the mentor, the co-mentor, and the educator

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### Article 146-a

The authorization of the mentor, the co-mentor, and the educator for mentorship, co-mentorship, and educator may terminate in the course of the specialty, that is, sub-specialty training in the event of termination of the employment contract, a longer period of absence due to illness and injury, in the event of prevention to work due to pregnancy, childbirth and maternity, or a longer period of absence due to professional development abroad.

## Agreement between the public healthcare institution and the resident

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### Article 147

(1) The public healthcare institution that have approved the specialty training shall conclude an agreement with the resident, regulating the mutual rights and obligations concerning the implementation of the specialty training, the time that the resident needs to spend working in the institution after the completion of the specialty training, and that, regarding the specialty training that lasts up to five years, the resident should work in the institution for at least five years, and that, regarding the specialty training that lasts more than five years, the resident should work in the institution for at least ten 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 social insurance contributions, 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 specialty training 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 sent him/her to specialty training referred to in paragraph (1) of this Article upon his/her personal request or due to his/her fault cannot be lower than five times the amount of the specialty training 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.

## Agreement between the public healthcare institution and the sub-specialty trainee

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### Article 147-a

(1) The public healthcare institution that have approved the sub-specialty training shall conclude an agreement with the sub-specialty trainee, regulating the mutual rights and obligations concerning the implementation of the sub-specialty training, the time that the sub-specialty trainee needs to spend working in the institution after the completion of the sub-specialty training, that is, regarding the sub-specialty training that lasts up to two years, the sub-specialty trainee should work in the institution for at least five years after the completion of the sub-specialty training, that is, regarding the sub-specialty training that lasts more than two years, the sub-specialty trainee should work in the institution for at least seven 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 social insurance contributions, 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 sub-specialty training of the sub-specialty trainees shall be provided by their employers.

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

## Criteria and program for the needs of specialized and sub-specialized personnel

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### Article 148

(1) The Government of the Republic of Macedonia shall adopt a four-year program for the needs of specialist and sub-specialist personnel in accordance with the network of healthcare institutions. The need of specialist and sub-specialist personnel shall be determined in the program each year separately based on the number and the age structure of the specialists, that is, sub-specialists, the waiting time according to the electronic list of scheduled examinations and interventions, and the need for using specialist and consultative and hospital health services in the municipality, that is, the public healthcare institution.



(2) For the purpose of implementing the program, the public healthcare institutions shall be obliged to ensure funds in the amount required for delivery of the specialty, that is, sub-specialty training.

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

(4) The Specialty Training 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 Specialty Training Council.

## Program for professional development in the healthcare institutions in the network

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### 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 specialty, that is, the sub-specialty training 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 send healthcare workers and healthcare co-workers to specialty, that is, sub-specialty training, 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 sending to specialty, that is, sub-specialty training by means of a public or internal announcement for specialty, that is, sub-specialty training of the employees in the public healthcare institution which sends them to specialty, that is, sub-specialty training. It shall send to specialty training according to the following criteria and proportion: 70% for the GPA score of the candidate at the university, 20% for the length of service and 10% for the success achieved in the subject in the field in which

the specialty training is awarded. It shall sent to sub-specialty training according to the following criteria and proportion: 70% for the GPA score of the candidate at the university, 20% for the success achieved in the subject in the field in which the specialty training is awarded and 10% from the scores for the length of service. The manner of calculating the weighted GPA scores of the candidate at a university and the success in the subject shall be determined by the minister of health.

(5) The act for sending to specialty, that is, sub-specialty training, together with the proofs for meeting the requirements and a proof of approval of the specialty, that is, sub-specialty training 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 specialty, that is, sub-specialty training.

(6) The higher education institutions shall keep records of the healthcare workers, that is, healthcare co-workers who have been sent, have applied for enrollment and who are attending specialty, that is, sub-specialty training, as well as of the fulfillment of the specialty, that is, sub-specialty training 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 specialty, that is, sub-specialty training 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 delivering specialty, that is, sub-specialty training announced in the mass media.

## Opportunity for taking specialty training by healthcare workers and co-workers from private healthcare institutions

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### 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 specialty, that is, sub-specialty training in accordance with the specialty training 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.

## Opportunity to continue the specialty, that is, sub-specialty training at the costs of a public healthcare institution

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### Article 150-a

(1) The healthcare workers and healthcare co-workers employed in a public healthcare institution and enrolled in a specialty, that is, sub-specialty training in accordance with Article 150 of this Article may file a request to the public healthcare institution in which they

are employed to continue the specialty, that is, sub-specialty training at the costs of the healthcare institution in which they are employed.

(2) If the specialty, that is, sub-specialty training in which the healthcare worker, that is, healthcare co-worker is enrolled is a branch of medicine, dental medicine, pharmacy, and other fields that compose the activity of the healthcare institution, as well as if the specialty, that is, sub-specialty training is in line with the program for the needs of specialist and sub-specialist personnel referred to in Article 148 of this Law, and if the healthcare worker, that is, healthcare co-worker meets the conditions referred to in Article 141 of this Law, the public healthcare institution shall approve the request referred to in paragraph (1) of this Article by adopting a decision.

(3) The public healthcare institution which has approved the request referred to in paragraph (1) of this Article shall cover the costs for carrying out the specialty, that is, sub-specialty training as of the day of the adoption of the decision referred to in paragraph (2) of this Article.

#### Article 150-b

(1) The public healthcare institution shall continue to compensate the costs for the specialty, that is, sub-specialty training of the healthcare workers, that is, healthcare co-workers enrolled in specialty, that is, sub-specialty training pursuant to Article 150 of this Law who are employed in a public healthcare institution carrying out a specialist and consultative and hospital activity as of the day of conclusion of the employment contract, provided that the following conditions are met:

- the specialty, that is, sub-specialty training in which the healthcare worker, that is, healthcare co-worker is enrolled is for a branch of medicine, dental medicine, pharmacy, and other fields that compose the activity of the healthcare institution,
- if in line with the program for the needs of specialist and sub-specialist personnel referred to in Article 148 of this Law, and
- if the healthcare worker, that is, healthcare co-worker meets the conditions referred to in Article 141 of this Law.

(2) The employment of the healthcare workers, that is, healthcare co-workers referred to in paragraph (1) of this Article shall terminate if the healthcare worker, that is, healthcare co-worker does not conclude a contract for specialty, that is, sub-specialty training with the public healthcare institution in which he/she is employed.

### Specialty training during employment

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#### Article 150-c

(1) In the course of the specialty training, the resident who is enrolled in specialty training pursuant to Article 150 of this Law may, outside of his/her time spent for professional development referred to in Article 144-c of this Law, also work:

- as a chosen doctor;
- in the on-duty services of the public healthcare institutions;
- in the services for emergency medical care of the public healthcare institutions, and
- in the exercise of the right of the patients to health protection at primary level in a medical center with a head office in the area which covers the municipality where the place of residence of the patient is located pursuant to Article 32-a of this Law, that is, as a rural doctor.

(2) Provided that the resident referred to in paragraph (1) of this Article works as a chosen doctor, he/she shall be entitled to use the seal of a doctor of general medicine and to render, that is, to continue rendering healthcare services to the patients who have chosen him/her as a chosen doctor pursuant to Article 32 of this Law, as well as to hire a doctor of medicine who shall replace him/her during the time spent for professional development referred to in Article 144-c of this Law.

(3) If the resident referred to in paragraph (1) of this Article works in the on-duty services of the public healthcare institutions, in the services for emergency medical care, and in a medical center at primary level, in the exercise of the right of the patients to health protection at primary level in a medical center in which a healthcare activity at primary level is carried out and which has a head office in the area which covers the municipality where the place of residence of the patient is located pursuant to Article 32-a of this Law, he/she shall be entitled to compensation, depending on the number of working hours that the resident spends in these services.

## Program for co-financing of specialty, that is, sub-specialty training of healthcare workers and healthcare co-workers employed in private healthcare institutions, other legal entities, and unemployed persons

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### Article 150-d

(1) The healthcare workers and the healthcare co-workers that are not employed in a public healthcare institution may, for the purpose of starting or completing the specialty, that is, sub-specialty training, apply to a public announcement for enrollment in co-financed private specialty, that is, sub-specialty training published by the Ministry of Health, in accordance with a program for co-financing of specialty, and sub-specialty training adopted by the Government of the Republic of Macedonia (hereinafter: co-financing program).

(2) The co-financing program referred to in paragraph (1) of this Article shall determine the number of vacancies for specialty or sub-specialty training per municipalities and public healthcare institutions and the amount of the funds for co-financing provided by the Ministry of Health. The amount of the funds for co-financing for each branch of specialty, for each municipality and a public healthcare institution shall be determined in accordance with the number and the age structure of the residents, that is, sub-specialty trainees, the waiting time according to the electronic list of scheduled examinations and interventions,

and the need for using specialist and consultative and hospital health services in the municipality, that is, the public healthcare institution.

(3) As an exception to Article 157 of this Law, the healthcare workers, that is, the healthcare co-workers referred to in paragraph (1) of this Article, after completing the specialty, that is, the sub-specialty training shall be employed in the public healthcare institution where he/she has applied for specialty, that is, sub-specialty training without publishing an announcement.

(4) The public announcement for enrollment of co-financed private specialty, that is, sub-specialty training referred to in paragraph (1) of this Article shall last 30 days as of the day of its publication at the most.

(5) The healthcare workers, that is, healthcare co-workers who have applied to the public announcement referred to in paragraph (1) of this Article shall be selected on the basis of the following criteria:

1) the GPA from all of the subjects of the first cycle of higher education (hereinafter: the GPA) to be awarded 50 points in total and

2) the examination which consist of two parts and to be awarded 50 points in total:

- a professional test which is to be awarded 35 points and

- knowledge of the English language which is to be awarded 15 points.

(6) Points for the GPA referred to in paragraph (5) point 1) of this Article shall be awarded according to the GPA from all of the subjects of the first cycle of higher education completed by the healthcare worker, that is, the healthcare co-worker and the ranking of the university at the ranking list of domestic universities in accordance with the Law on Higher Education.

(7) The manner of awarding points to the candidates based on the GPA referred to in paragraph 5 point 1) of this Article, the database of questions and the number of posed questions at the examination, and the manner of conducting the examination shall be determined by the minister of health.

(8) The Ministry of Health, in cooperation with the Doctors' Chamber, shall organize the examination referred to in paragraph (5) point 2) of this Article.

(9) As an exception to paragraph (5) of this Article, in the case of applying for completion of the started specialty, that is, sub-specialty training as part of the residents, that is, sub-specialty trainees co-financing program, the selection of the healthcare workers, that is, healthcare co-workers shall be made based on the following criteria:

1) the GPA from all of the subjects of the first cycle of higher education (hereinafter: the GPA) to be awarded 30 points in total;

2) the duration of the residency, that is, sub-residency shown as number of months of residency, that is, sub-residency (hereinafter: length of residency, that is, sub-residency) to

be awarded 40 points; and

3) the examination which consist of two parts and is to be awarded 30 points in total:

- a professional test which is to be awarded 20 points and
- knowledge of the English language which is to be awarded 10 points.

(10) Points for the length of the residency, that is, sub-residency referred to in paragraph (9) point 2) of this Article shall be awarded according to the number of months that the resident, that is, the sub-specialty trainee has spent doing residency, that is, sub-residency, and the resident, that is, the sub-specialty trainee who has the biggest number of months of residency, that is, sub-residency shall be awarded 40 points.

(11) The healthcare workers, that is, the healthcare co-workers referred to in paragraph (1) of this Article shall start the residency, that is, sub-residency after they receive a decision on enrollment in specialty, that is, sub-specialty training adopted by the Ministry of Health in accordance with the ranking list compiled on the basis of the points calculated in accordance with paragraph (5), that is, paragraph (9) of this Article.

(12) The Ministry of Health, the public healthcare institutions, and the healthcare worker, that is, the healthcare co-worker referred to in paragraph (11) of this Article shall conclude an agreement for specialty, that is, sub-specialty training that regulates the mutual rights and obligation regarding the delivery of the specialty, that is, the sub-specialty training, the obligation to work in the public healthcare institution where he/she has been employed in accordance with paragraph (3) of this Article, as well as the amount of the funds that he/she should compensate in case of early quitting from the institution on his/her request or at his/her fault and the appropriate guarantee in case of failure to fulfill the obligation towards the public healthcare institution.

(13) The duration of the obligation of the resident, that is, the sub-specialty trainee to work in the public healthcare institution where he/she has been employed in accordance with paragraph (3) of this Article shall be regulated in the agreement for specialty, that is, sub-specialty training referred to in paragraph (12) of this Article in accordance with Articles 147 paragraph (1) and 147-a of this Law.

(14) The resident who has been employed in accordance with paragraph (3) of this Article and who, on his/her request or at his/her fault, are not no fulfill the obligation referred to in paragraph (13) of this Article shall be obliged to compensate the funds to the Ministry of Health in five times the amount of the amount of the funds designated from the co-financing program for his/her specialty, and the sub-specialty trainee in the four time the amount of the amount of the funds designated from the co-financing program for his/her sub-specialty training.

Co-financing specialty, that is, sub-specialty training in pediatrics and gynecology and obstetrics

## Article 150-e

(1) The co-financing program referred to in Article 150-d paragraph (1) of this Law shall cover also the doctors of medicine who enroll in specialty, that is, sub-specialty training in pediatrics or in specialty training in outpatient pediatrics, as well as in specialty, that is, sub-specialty training in gynecology and obstetrics.

(2) The doctors of medicine referred to in paragraph (1) of this Article who have completed the specialty, that is, the sub-specialty training on time shall conclude an agreement with the Health Insurance Fund of Macedonia for a chosen doctor pediatrician, that is, gynecologist and their capitation shall be calculated stimulative in a value of 1000 points on a monthly basis, in duration of 36 months, after which the principle of stimulation is not to be applied, but the capitalization shall be calculated in accordance with the regulations on the manner of payment of health services in the primary level of health protection.

(3) The provisions of Article 150-d paragraphs (1), (2), (4), (5), (6), (7), (8), (9), (10), (11) and (12) of this Law shall apply also to the enrollment in specialty, that is, sub-specialty training of the doctors of medicine referred to in paragraph (1) of this Article.

(4) The Ministry of Health and the doctors of medicine referred to in paragraph (1) of this Article shall conclude an agreement on specialty, that is, sub-specialty training that regulates the mutual rights and obligation regarding the delivery of the specialty, that is, the sub-specialty training, the obligation to work in a public or private healthcare institution in the Republic of Macedonia after acquiring the status of a specialist, that is, a sub-specialist, the appropriate guarantee in case of failure to fulfill the obligation, as well as the amount of the funds that he/she should compensate in case of failure to fulfill such obligation on his/her request or at his/her fault.

(5) The duration of the obligation of the resident, that is, the sub-specialty trainee to work in a public or a private healthcare institution in the Republic of Macedonia shall be regulated in the agreement for specialty, that is, sub-specialty training referred to in paragraph (4) of this Article in accordance with Articles 147 paragraph (1) and 147-a of this Law.

(6) The resident who, on his/her request or at his/her fault, fails to fulfill the obligation referred to in paragraph (5) of this Article shall be obliged to compensate the funds to the Ministry of Health in five times the amount of the amount of the funds designated from the co-financing program, and the sub-specialty trainee in the four time the amount of the amount of the funds designated from the co-financing program for his/her sub-specialty training.

## Specialty training of a foreign citizen – a healthcare worker

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### Article 151



(1) The Ministry of Health may approve specialty, that is, sub-specialty training 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 specialties and sub-specialties completed abroad, as well as parts of specialties and sub-specialties completed abroad by residents and sub-specialty trainees who are enrolled in a specialty, that is, sub-specialty training in the Republic of Macedonia and who are sent to carry out and complete parts of their specialty, that is, sub-specialty training or the overall residency abroad in accordance with the program of the Government of the Republic of Macedonia.

(3) In order to recognize the specialties and sub-specialties 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) As an exception to paragraph (3) of this Article, the Ministry of Health shall recognize the parts of specialties and sub-specialties completed abroad by the residents and sub-specialty trainees who are enrolled in a specialty, that is, sub-specialty training in the Republic of Macedonia and who are sent to carry out and complete parts of their specialty, that is, sub-specialty training or the overall residency abroad in accordance with the program of the Government of the Republic of Macedonia by adopting a decision based on a delivered certificate issued by the foreign public healthcare institution, that is, the foreign higher education institution, without conducting a procedure and without forming a commission.

(5) The manner of recognizing and the documents required for recognition of the specialties and sub-specialties completed abroad, as well as the manner of keeping records of the recognized specialties and sub-specialties completed abroad, shall be prescribed by the minister of health.

## Application of the provisions on specialty training

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### Article 151-a

(1) The Articles 144-a to 144-o of this Law shall apply to the specialty training of healthcare workers who have completed a higher education in the field of medicine.

(2) Articles 144-a to 144-o and 145-a of this Law shall not apply to:

- healthcare workers with a university degree in the field of medicine who specialize in epidemiology, immunology, medical genetics and molecular biology, clinical pharmacology, medical biochemistry, labor medicine, medical microbiology with parasitology, nuclear medicine, pathological anatomy, forensic medicine, social medicine and public health, sports medicine, and hygiene with health ecology, family medicine and transfusion,



- healthcare workers with a university degree in the field of pharmacy who specialize in the field of health specialty training for graduated pharmacists, and
- healthcare workers with a university degree in the field of dentistry who specialize in the field of health specialty training for doctors of dentistry.

## 5. Duties of healthcare workers and healthcare co-workers

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### Liability of the healthcare worker

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#### 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.

### Liability of the healthcare workers and healthcare co-workers for applying and observing the principles and rules of conduct and operation

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#### Article 152-a

- (1) The healthcare workers and healthcare co-workers shall be obliged, in the course of their operation, taking actions, and conduct, to apply and observe the principles and rules of conduct and operation determined by the minister of health by means of a protocol pursuant to Article 27 paragraph (5) of this Law, for the purpose of ensuring application and observance of the principles of legality, professional integrity, efficiency, effectiveness and dedication in the performance of their official duties.
- (2) The healthcare workers and healthcare co-workers shall be disciplinary liable for a disciplinary offense in the event of acting contrary to paragraph (1) of this Article and the provisions set out by the protocol referred to in Article 27 paragraph (5) of this Law.

### Professional secret

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#### 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

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### Article 154

(1) A violation of the 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

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### 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

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### Classification of positions

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#### 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, and
- 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, professional 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

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### Article 155-b

(1) The following levels of positions of providers of public health services shall be determined within the category A:

- level A1 managerial workers of internal organizational units,
- level A2 doctor of medicine, doctor of dentistry, graduated pharmacist - doctor of sciences - full-time professor,
- level A3 doctor of medicine, doctor of dentistry, graduated pharmacist - doctor of sciences - scientific counselor,
- level A4 doctor of medicine, doctor of dentistry, graduated pharmacist - part-time professor,
- level A5 doctor of medicine, doctor of dentistry, graduated pharmacist - doctor of sciences - senior scientific counselor,
- level A6 doctor of medicine, doctor of dentistry, graduated pharmacist - doctor of sciences - associate professor,
- level A7 doctor of medicine, doctor of dentistry, graduated pharmacist - doctor of sciences - scientific associate,
- level A8 doctor of medicine, doctor of dentistry, graduated pharmacist - doctor of sciences - assistant,
- level A9 doctor of medicine, doctor of dentistry, graduated pharmacist - doctor of sciences,
- level A10 doctor of medicine, doctor of dentistry, graduated pharmacist - sub-specialist,

- level A11 doctor of medicine, doctor of dentistry, graduated pharmacist - specialist - primarius,
- level A12 doctor of medicine, doctor of dentistry, graduated pharmacist - specialist master of sciences,
- level A13 doctor of medicine, doctor of dentistry, graduated pharmacist - assistant,
- level A14 doctor of medicine, doctor of dentistry, graduated pharmacist - specialist and others,
- level A15 doctor of medicine, doctor of dentistry, graduated pharmacist - primarius,
- level A16 doctor of medicine, doctor of dentistry, graduated pharmacist - master of sciences, and
- level A17 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 have active knowledge in one of the three most commonly used languages in the European Union (English, French, German), active knowledge in office computer programs, and other special work competencies determined by the act on systematization of jobs for the respective job.

(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.

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

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### Article 155-c

(1) 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 physiotherapist 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, physiotherapist in charge and others, and
- level B3 graduated nurse and nurse - specialist, graduated radiologic technologist, graduated physiotherapist, graduated transfusiologist, graduated speech therapist

(integrated studies at the faculty of medicine) and others.

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

(3) The employees of category B should have active knowledge in one of the three most commonly used languages in the European Union (English, French, German), active knowledge in office computer programs, and other special work competencies determined by the act on systematization of jobs for the respective job.

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

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### Article 155-d

(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 physiotherapist, 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

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### Article 155-e

(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, physiotherapist at reanimation, nurse in intensive care, midwife in birthing room, nurse at dialysis, nurse physiotherapist 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, physiotherapist, 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

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### 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 - doctors of sciences and 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 should have active knowledge in one of the three most commonly used languages in the European Union (English, French, German), active knowledge in office computer programs, and other special work competencies determined by the act on systematization of jobs for the respective job.

## Auxiliary-technical persons

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## 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 other), 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 other) and others,
- 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 guard - 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 give 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 give 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 give at least primary education:

- subgroup 2, category A level A4



- subgroup 4, category A level A3
- subgroup 5, category A, level A2, level A3 и A4,
- subgroup 5, category B, level B3, B7, B8, B9 и 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.

## Employment in accordance with the Annual Plan and the needs of the public healthcare institutions

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### Article 155-h

- (1) The director of the public healthcare institution, upon a previous opinion from the Ministry of Information Society and Administration and upon a previous consent from the Ministry of Health, shall adopt an Annual Plan for Employment of Administrative Servants and Auxiliary-technical Persons for the following year, in accordance with the Law on Public Sector Employees.
- (2) The providers of public services in the field of health shall be employed in accordance with the needs of the public healthcare institutions.
- (3) The procedures for filling in vacancies under this Law shall be conducted upon a previous notification for provided funds from the Ministry of Finance. The director of public healthcare institution through the Ministry of Health shall submit a request for obtaining consent for provision of funds to the Ministry of Finance.
- (4) The procedure for employment of healthcare workers and healthcare co-workers in the public healthcare institutions shall be conducted in accordance with this Law.
- (5) The employment referred to in paragraphs (2) and (4) of this Article shall be conducted by concluding a contract for an indefinite period of time.
- (6) As an exception to paragraph (5) of this Article, in case of inability to conduct the procedure for employment for an indefinite period of time, and where there is a need in the public healthcare institution for healthcare workers and/or healthcare co-workers, for the purpose of unobstructed provision of the public service in the institution, they may be employed by concluding an employment contract for a definite period of time of up to five years.
- (7) The provisions of this Law shall entirely apply to the employees referred to in paragraph (6) of this Article.
- (8) If the employees referred to in paragraph (6) of this Article enroll in specialty, that is, sub-specialty training where they are posted by the public healthcare institution where they are employed, the contract for specialty, that is, sub-specialty training shall be concluded in

accordance with this Law and the employment shall be transformed into employment for an indefinite period of time after the expiry of five years.

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

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

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#### 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

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#### 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, and
- taking over a healthcare worker, that is, a healthcare co-worker from one to another healthcare institution.

### General and special requirements for employment

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#### 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

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### 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

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### Article 160

(1) The management body of the healthcare 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:
  - a professional 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 professional part (a test).

(4) The commission for preparation of tests for the professional 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 professional part and the tests for the knowledge of a world language.

(6) The tests for the professional 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

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### 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, make an interview and shall 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

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### 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

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### 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

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### 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.

A healthcare worker holding a higher education degree in the field of medicine, dentistry or pharmacy and a license for work, who carries out a healthcare activity in a private healthcare institution may be taken in a public healthcare institution if the need for continuous carrying out of the activity of the public healthcare institution is previously determined by the Ministry of Health and if the healthcare worker, the director of the public healthcare institution where he/she should be taken, the Ministry of Health and the Fund agree thereof.

(3) A healthcare worker who has completed secondary education, two-year post secondary education, or higher education or has 180 ECTS in the field of medicine (medical nurses, medical technicians and radiology technologists), who carries out a healthcare activity in a private healthcare institution, and who has work experience in the profession of at least three years in a public healthcare institution or work experience in the profession of at least seven years in a public or private healthcare institution which carries out a hospital healthcare activity, may be taken in a public healthcare institution at secondary and tertiary level, without publishing an announcement, on the basis of a written request of the director explaining the need of taking and a written consent from the healthcare worker, the directors, that is, the director of the public healthcare institution where he/she should be taken, the Ministry of Health, and the Health Insurance Fund of Macedonia.

(4) The healthcare workers who have completed secondary education, two-year post secondary education, and higher vocational education or have 180 ECTS in the field of medicine and dentistry who, by taking over from the public healthcare institutions, have been employed in the 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. 38/1991, 46/1993, 55/1995, 10/2004, 84/2005, 111/2005, 65/2006, 5/2007, 77/2008, 67/2009, 88/2010, 44/2011 and 53/2011), whose employment has terminated in such institutions because of termination of the work of the institutions or upon termination of the right to lease due to death or exercise of the right to pension of the healthcare worker to whom the premises and the equipment have been leased and with whom, on the day of death or exercise of the right to pension, have been assigned at a job as part of the team, but do not fulfill the requirements for exercise of the right to age pension, shall be employed in the public healthcare institution wherefrom they have been taken over, that is, in another public healthcare institution where there is a need of such type of healthcare workers, provided that there is no vacancy in the public healthcare institution wherefrom they have been taken over.

(5) The healthcare workers referred to in paragraph (4) of this Article shall submit a request for exercise of the right referred to in paragraph (4) of this Article to the Ministry of Health. Documents proving that they meet the requirements referred to in paragraph (4) of this

Article shall be attached to the request. The documents shall be submitted in their original form or as a notary verified copy.

(6) The Ministry of Health, within a period of 30 days as of the receipt of the request referred to in paragraph (5) of this Article, shall decide on the request based on the submitted documentation referred to in paragraph (5) of this Article and shall issue a consent for employment of the healthcare worker referred to in paragraph (4) of this Article in the public healthcare institution wherefrom he/she has been taken over, that is, in another public healthcare institution where there is a need of such type of healthcare workers, provided that there is no vacancy in the public healthcare institution wherefrom he/she has been taken over.

(7) The public healthcare institution referred to in paragraph (6) of this Article shall register the healthcare worker referred to in paragraph (3) of this Article as employed in accordance with this Law, based on the consent from the Ministry of Health.

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

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

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#### 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

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#### 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 a grade point average of at least eight for all university study cycles completed by the candidate (hereinafter: the grade point average) and
- to have active knowledge in one of the three most commonly used languages in the European Union (English, French, German), active knowledge in office computer programs, and other special work competencies determined by the act on systematization of jobs for the respective job.

(2) As an exception, the candidate who has completed specialty or sub-specialty training 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.

## Selection of a candidate

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### 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 specialty, that is, sub-specialty, with at least ten years of work experience after the specialty training, 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 grade point average for 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

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### Article 164-d

(1) The written and the oral examination shall be held in premises for holding an examination, equipped specially for holding 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 holding 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 holding 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 awarded 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

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

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#### 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.

### Physical and psychological integrity, personality, dignity, and safety of healthcare workers and healthcare co-workers

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#### Article 165-a

(1) A healthcare worker with completed higher education, two-year post-secondary education, and secondary education, and a healthcare worker with completed higher education performing a healthcare activity and rendering healthcare services shall be regarded as an official who performs an official duty on the basis of an authorization granted by this Law.

(2) The physical and psychological integrity, personality, and dignity of the healthcare workers and healthcare co-workers referred to in paragraph (1) of this Article, as well as their safety, must be respected, and these healthcare workers and healthcare co-workers shall be entitled to protection of these rights when performing a healthcare activity and when rendering healthcare services as their official duty.

(3) Assault on a healthcare worker and a healthcare co-worker when performing a healthcare activity and when rendering healthcare services as an official duty shall be regarded as assault on an official when performing a healthcare activity and when rendering healthcare services as official duty.

### Performance of duties

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#### 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

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### 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

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### 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

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### 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 provision that the engagement of the healthcare workers or the healthcare co-workers is not for the purpose of recommending, prescribing, buying, procuring, selling or marketing a particular medications,
- 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 and obligation of wearing a tag

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### Article 169

(1) The healthcare worker, that is, healthcare co-worker shall be obliged, during the working hours, at his/her workplace, to wear a tag in a visible place in the form of a card, containing a photo of the healthcare worker, that is, healthcare co-worker, the name, the position and the healthcare institution where he/she works.

(2) The director of the healthcare institution shall be obliged to organize and ensure that the healthcare workers, that is, healthcare co-workers wear a tag in a visible place in accordance with paragraph (1) of this Article and he/she shall be obliged to initiate a disciplinary procedure against the healthcare worker, that is, healthcare co-worker who does not wear the tag referred to in paragraph (1) of this Article, within a period of seven days as of the day he/she finds out about the reason for initiating a disciplinary procedure.

## Professional training and development

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### 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

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#### 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 in which he/she is employed within a period of one month as of the return from the professional training and/or professional development.

## Right to protection

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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.

(2) For the purpose of maintaining and upgrading the professional knowledge, abilities, and skills, the healthcare worker, that is, healthcare co-worker elected or appointed to a state or public office established by law, shall be entitled to, following the termination of the working hours of the state administrative body or the local self-government unit, public enterprise, agency or another institution established by law, temporarily perform the tasks and duties of the healthcare worker, that is, healthcare co-worker in the public healthcare institution in which his/her employment is in abeyance pursuant to paragraph (1) of this Article, for which he/she shall be personally, and disciplinary liable, as well as he/she shall be liable for the damage that he/she has caused at work or in relation to the work in the public healthcare institution.

(3) As an exception to paragraph (2) of this Article, the healthcare worker, that is, healthcare co-worker who is elected or appointed to a state or public office established by law, may also temporarily perform a healthcare activity in another public healthcare institution, other than the public healthcare institution in which his/her employment is in abeyance pursuant to paragraph (1) of this Article, by an approval from the Ministry of Health.

(4) The healthcare worker, that is, healthcare co-worker who is elected or appointed to a state or public office established by law, in the cases referred to in paragraphs (2) and (3) of this Article, shall be entitled to perform the tasks and duties of the healthcare worker, that is, healthcare co-worker for a period of 15 hours per week at the most for which he/she shall not be entitled to payment of salary and salary compensations, salary supplements and allowances for work-related costs under conditions and criteria determined by law, collective agreement, and employment contract pursuant to Article 165 of this Law, nor shall be entitled to payment of compensation on any other grounds.

(5) The healthcare worker with a higher education in the field of medicine who is elected or appointed to a state or public office established by law shall have the right to use the seal for performing a healthcare activity in the cases referred to in paragraphs (2) and (3) of this Article.

## Return to work

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### 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 that carry out a healthcare activity at tertiary level

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## Period of monitoring

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### 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, sub-specialist, that is, as a doctor of dentistry, specialist, that is, sub-specialist, and as a pharmacist, specialist, that is, sub-specialist. 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, has participated 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, sub-specialist 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 sub-specialist 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

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### 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 sub-specialists abroad, and the Ministry of Health shall be obliged to plan them in the annual programs for training of doctors of medicine, specialists and sub-specialists.

(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

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### 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

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### Personal liability

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#### 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

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#### 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

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#### 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

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### 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

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### 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

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### 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

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### 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) refusal 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) refusal to perform the tasks and duties of the job to which he/she is assigned or refusal of 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) receipt of gifts or other type of benefits contrary to the law, or receipt or acceptance of an offer to receive a gift, money or any other type of benefit in order to recommend, prescribe or procure particular medications;
- 10) abuse of the status or exceeding the authorizations in the performance of the activities;
- 11) abuse of the sick leave;
- 12) disclosure of 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-compliance 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) offensive or violent behavior;
- 17) unjustifiable refusal to participate in electoral bodies; and
- 18) obstruction of 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.
- 19) taking actions contrary to Article 39-a paragraph (3) of this Law for the first time,
- 20) non-application and non-observance of the principles and rules of conduct and operation upon which the healthcare workers, that is, healthcare co-workers are obliged to act when doing the job for the purpose of ensuring application and observance of the principles of legality, professional integrity, efficiency, effectiveness and dedication in the performance of their official duties, determined by the minister of health by the rulebook for hospital culture pursuant to Article 27 paragraph (5) of this Law,
- 21) failure to appear at work in the public healthcare institution and non-performance of the tasks under the travel order referred to in Article 28 paragraph (4) of this Law, by the healthcare worker, that is, healthcare co-worker who is sent to work based on the travel order, shall constitute a disciplinary offense;
- 22) non-performance of an examination and/or intervention at the appointment scheduled through the electronic list of scheduled examinations and interventions by the healthcare worker, that is, healthcare co-worker without having objective and justifiable reasons pursuant to Article 39-b paragraph (2) of this Law, or starting the examination, that is, intervention late because of the healthcare worker, that is, healthcare co-worker without having objective and justifiable reasons pursuant to Article 39-b paragraph (2) of this Law;
- 23) failure of the head of the internal organizational unit in the healthcare institution to send the notification to the management body of the public healthcare institution pursuant to Article 39-b paragraph (8) of this Law;



- 24) failure to establish a commission for conducting a disciplinary procedure for the disciplinary offense and/or failure of the management body of the public healthcare institution to which the notification has been delivered to adopt a decision imposing a disciplinary measure pursuant to Article 39-b paragraph (8) of this Law;
- 25) absence of the person employed in the public healthcare institution who, pursuant to Article 39-b paragraph (14) of this Law, is obliged to always be present in the waiting room and to inform and explain the reasons, in a personal and direct communication, to all of the patients present in the waiting room and to the patients coming at the scheduled appointment, why the examination, that is, the intervention cannot be performed at the scheduled appointment, as well as to schedule a new appointment through the electronic list of scheduled examinations and interventions if the examination, that is, intervention has not been performed, failure to inform and explain, in a personal and direct communication, why there is no possibility the examination, that is, the intervention to be performed at the scheduled appointment, non-scheduling a new appointment through the electronic list of scheduled examinations and interventions if the examination, that is, intervention has not been performed;
- 26) failure of the healthcare worker rendering specialist and consultative services to attend training as referred to in paragraph (1) of this Article pursuant to Article 39-l paragraph (5) of this Law;
- 27) failure to enter the data that the particular medical equipment is not operational immediately upon the occurrence of the malfunction by the persons who keep, publish, and update the electronic list of scheduled examinations and interventions;
- 28) failure of the resident to record his/her presence through the system for recording the working time in the healthcare institution in which the module is delivered, in accordance with the time schedule for professional development;
- 29) entering or determining false and/or non-authentic data about the results of the operation in accordance with Article 219 paragraphs (3) and (4) of this Law, obtained by the healthcare worker or the manager of the internal organizational unit.

(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

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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

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### 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

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### 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

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### 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

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### 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

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### 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 offense 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 offense.

(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

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### 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.

## Procedure in the cases of liability of the healthcare workers and the healthcare co-workers for non-application and non-observance of the principles and rules of conduct and operation

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### Article 193-a

(1) The patient or the members of the patient's family shall file a complaint in a written form or orally on minutes to the director, that is, directors of the public healthcare institution, expressing their dissatisfaction with the non-application and non-observance of the principles and rules of conduct and operation by the healthcare workers and the healthcare co-workers, determined by the minister of health by a rulebook for hospital culture pursuant to Article 27 paragraph (5) of this Law. For the purpose of contacting the complainant, a contact telephone number and an exact address shall be mandatorily written in the complaint.

(2) The complainant referred to in paragraph (1) of this Article cannot be held liable, nor bear any harmful consequences due to the filing of the complaint, unless the complainant is making an untruthful statement in the complaint which could harm the honor and reputation of the healthcare worker, that is, healthcare co-worker due to which the healthcare worker, that is, healthcare co-worker may file a lawsuit.

(3) Acting upon the complaint referred to in paragraph (1) of this Article shall mandatorily include having a meeting with the complainant, collecting and analyzing the data on the facts and circumstances which are of importance for assessing the allegations in the complaint, and taking necessary actions and measures for exercising the rights of the complainant.

(4) The director, that is, the directors of the public healthcare institution shall also hold a meeting with the complainant referred to in paragraph (1) of this Article in the presence of a graduated lawyer employed in the public healthcare institution and/or the quality coordinator.

(5) The public healthcare institution shall not act upon an anonymous complaint, unless it is about matters of public interest determined by law.

(6) The director, that is, the directors of the public healthcare institution shall be obliged to give their response regarding the grounds of the complaint to the complainant referred to in paragraph (1) of this Article within a period of 15 days as of the receipt of the complaint.

(7) If, when acting upon the complaint, it is established that the rights of the complainant have been violated or that damage has been caused to him/her, the director, that is, directors of the public healthcare institution shall take the necessary measures pursuant to law for eliminating the violation of the right, that is, the damage caused, and the head of the internal organizational unit in the public healthcare institution in which the healthcare worker, that is, healthcare co-worker against whom the complaint is filed, is assigned, shall mandatorily file a request for initiation of a disciplinary procedure against that particular healthcare worker, that is, healthcare co-worker against whom the complaint has been filed pursuant to Article 152-a paragraph (2) of this Law.

(8) The director of the public healthcare institution shall establish a commission for conducting a disciplinary procedure for a disciplinary offense pursuant to Article 152-a paragraph (2) of this Law within a period of three days as of the day it has been established that the rights of the complainant have been violated or that damage has been caused to him/her, and he/she shall notify the complainant referred to in paragraph (1) of this Article that a commission has been established within a period of three days as of the establishment of the commission.

(9) The director of the public healthcare institution shall adopt a decision imposing a disciplinary measure for a disciplinary offense within a period of 15 days as of the initiation of the procedure, based on a proposal of the commission referred to in paragraph (8) of this Article. The director of the public healthcare institution shall deliver a copy of the decision imposing a disciplinary measure for a disciplinary offense to the complainant within a period of three days as of the adoption of the decision.

(10) If a notification about establishment of a commission for conducting a disciplinary procedure for a disciplinary offense, that is, decision imposing a disciplinary measure for a disciplinary offense is not received within the deadlines set out in paragraphs (8) and (9) of this Article, it shall be deemed that a commission for conducting a disciplinary procedure for a disciplinary offense is not established, that is, that a disciplinary measure for a disciplinary offense is not imposed.

(11) The complainant referred to in paragraph (1) of this Article shall be entitled to file a complaint to the Ministry of Health if he/she does not receive a notification about establishment of a commission for conducting a disciplinary procedure for a disciplinary offense, that is, a decision imposing a disciplinary measure for a disciplinary offense within the deadlines set out in paragraphs (8) and (9) of this Article. The patient shall attach a copy of the complaint in a written form, that is, a copy of the minutes in the case where the complaint is given orally on minutes to the complaint.

(12) In the case referred to in paragraph (11) of this Article, the minister of health shall determine a contractual penalty in accordance with Article 104 paragraph (4) of this Law in the amount of Euro 200 in Denar counter-value for the director of the public healthcare institution.

(13) In the case referred to in paragraph (11) of this Article, if a complaint has been delivered to the director of the public healthcare institution, but he/she has not established a commission for conducting a disciplinary procedure for a disciplinary offense, nor has adopted a decision imposing a disciplinary measure for a disciplinary offense, the director of the public healthcare institution shall be obliged to initiate a disciplinary procedure for a disciplinary offense against the healthcare worker, that is, healthcare co-worker against whom the complaint has been filed pursuant to paragraph (8) of this Article.

(14) In the case referred to in paragraph (13) of this Article, the minister of health shall determine a contractual penalty in accordance with Article 104 paragraph (4) of this Law in the amount of Euro 200 in Denar counter-value for the director of the public healthcare institution.

## Material liability

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### Termination of employment

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#### 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

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#### 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

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### 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

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### 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, and
- 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

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### 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,
- 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
- 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

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### 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

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### 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

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### Right to appeal

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#### 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

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### 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

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### Rights and obligations of administrative servants and auxiliary-technical persons in public healthcare institutions

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#### 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

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### Obligation for continuous carrying out of a healthcare activity

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#### 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

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#### Article 212

- (1) The roster, the beginning and the end of the working hours of the public healthcare institutions and of the chosen doctors 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 and of the chosen doctors 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 and the chosen doctors, the conditions and the time of rendering the health services, as well as the other rights and obligations of the public healthcare institutions and the chosen doctors 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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 head of the internal organizational unit who heads and organizes the process of work and the director, that is, the directors of the public healthcare institution in which the healthcare worker is employed shall assess and determine the results of the work of the healthcare worker and shall be responsible for their accuracy and authenticity.

(4) The data on the operation of the healthcare worker shall be entered in the integrated health information system in accordance with the regulations on records in the field of health, and the healthcare worker shall be held liable for the accuracy and authenticity of the data entered.

(5) 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 the law and collective agreement.

## Supplement for on-duty work and readiness

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### 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

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### Article 221

(1) If the performance of a particular 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

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### Article 222

(1) The healthcare workers – specialists employed in a healthcare institution, who perform a 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, 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 determined by the director, that is, the directors of the public healthcare institution where the healthcare workers – specialists who provide health services as an additional activity are employed, in accordance with the minister of health.. 20

(4) The price of the healthcare service provided through the additional activity shall be consisted of four components, that is, compensation for the costs of the healthcare institution for the intervention, that is, the diagnostic procedure, that is, for the specialist and consultative examination, the compensation for the team, revenue of the public healthcare institution, and a price for a day spent in a hospital.

(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

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### Article 223

(1) A team which has been approved the performance of an additional activity shall have the right, during one month:

- to make ten interventions at the most, each working day after 17:00 and/or on Saturdays and/or Sundays,
- to conduct ten diagnostic procedures at the most, on Saturdays and/or Sundays, and
- to render ten specialist and consultative services at the most, on Saturdays and/or Sundays.

(2) The right to make a team shall also have a healthcare worker from a private healthcare institution, members of which may be employees from a public and private healthcare institution.

(3) The team which performs an additional activity shall be obliged to enter in the electronic list of scheduled examinations and interventions the time scheduled for the interventions, the diagnostic procedures and the specialist and consultative services referred to in paragraph (1) of this Article. The team which performs an additional activity shall submit a request for scheduling a time for rendering health services to the director of the public healthcare institution who shall be obliged to make a schedule for use of free appointments. The team which is not satisfied with the schedule for use of the free appointments shall have the right to file a complaint to the managing board of the public healthcare institution which shall be obliged to decide on the complaint within a period of eight days as of the day of submission of the complaint.

(4) The team which performs an additional activity, as an exception to Article 39-a paragraph (12) of this Law, and in accordance with the patient, shall be obliged to cancel the appointment scheduled for using the same health service through the electronic list of scheduled examinations and interventions.

(5) The health service provided as an additional activity shall be completely covered by the patient as an insured or 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

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### 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 medications, 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 procurement 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 procurement 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

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### 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 medications 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

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### 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

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### 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

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### 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 specialty, that is, sub-specialty and the experience in the respective field of specialty, that is, sub-specialty 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) 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, sub-specialists from other healthcare institutions." 21

## Cases that are reviewed at the meetings of the expert commission for review of cases of patients with malignant diseases

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### 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

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### 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 member 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

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### 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

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### 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

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### 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

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### 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

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### 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 intraoperative finding does not correspond to the preoperative diagnostic.

## Protocol for safe surgery

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### Article 226-j

(1) The surgical interventions in the healthcare institutions shall be performed according to the protocol for safe surgery which includes checking the actions taken according to the surgical safety checklist before, during, and after the completion of the surgical intervention, for the purpose of lowering the possibility of a mistake when performing the surgical intervention.

(2) The minister of health shall determine the protocol for safe surgery and the form and the contents of the surgical safety checklist.

(3) Following the adoption of the protocol referred to in paragraph (2) of this Article, the Ministry of Health shall be obliged to publish it immediately on the website of the Ministry and in the "Official Gazette of the Republic of Macedonia".

## Clinical pathway for diagnostics and treatment of malignant diseases

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### Article 226-k

(1) The healthcare treatment of the patients suffering from malignant diseases which covers diagnostics and treatment of malignant diseases shall be performed in line with the clinical pathway by which the obtaining of a priority status of the patients suffering from malignant diseases in view of the rendering healthcare services, the longest period of time as of the

time of scheduling up to the time of the examinations and interventions, and the mandatory examinations and interventions of the patients suffering from malignant diseases is particularly established.

(2) The minister of health shall determine the course of the healthcare treatment of the patients suffering from malignant diseases referred to in paragraph (1) of this Article.

(3) Following the adoption of the clinical pathway referred to in paragraph (2) of this Article, the Ministry of Health shall be obliged to publish it immediately on the website of the Ministry and in the "Official Gazette of the Republic of Macedonia".

## IX. LICENSES FOR CARRYING OUT A HEALTHCARE ACTIVITY IN THE NETWORK OF HEALTHCARE INSTITUTIONS

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### Determination of the license and the license holders

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#### 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

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## 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

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### 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 22*

(22) The minister of health shall approve the tender documentation.

## License granting procedure

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### 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 that 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 23*

(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,
- *abolished 24*
- 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 Ministry 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

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### Article 231

(1) In the process of granting a license, in the case of a same acceptable most favorable bid, priority over the other criteria for selection of the most favorable bid shall be the current status of the candidate who applied at the announcement as a lessee of parts of the medical center, 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).

(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.

#### Article 231-a

(1) The commission which conducts the public bidding, set up by the director upon a proposal of the governing board of the public healthcare institution, shall be obliged to publish an announcement in the "Official Gazette of the Republic of Macedonia" for leasing premises by public bidding within a period of 15 days as of the adoption of the decision of the governing board for leasing premises, and the governing board of the public healthcare institution shall be obliged to adopt a decision on leasing premises for a period of at least three months prior to the expiry of the contract of lease of the premises concluded with the previous lessee.

(2) The commission referred to in paragraph (1) of this Article shall be composed of three members from among the employees in the public healthcare institution leasing the premises. The president of the commission shall be selected from among the members of the commission.

(3) The Public Enterprise "Official Gazette of the Republic of Macedonia" shall be obliged to publish the announcement for public bidding free of charge within a period of ten days as of the day of receipt of the request for publishing the announcement at the latest.

(4) If necessary, the announcement for public bidding may also be published in the daily press.

(5) In the case of unsynchronized publication of the announcement for public bidding, the

deadline for the public bidding published in the "Official Gazette of the Republic of Macedonia" shall be valid.

(6) The announcement for public bidding of the premises shall particularly contain the following:

- data on the immovable property which is being leased (place, street and number, cadastre municipality, cadastre parcel, number of the property certificate in which the purpose of the premises is entered, and the purpose can for residential or business premises, and area),
- initial amount of the rental fee which is subject to the public bidding,
- amount of the monetary deposit that should be paid for participation in the public bidding,
- account at which the deposit is paid,
- deadline for payment of the deposit,
- requirements that the bidders have to meet in order to participate in the public bidding,
- deadline for submission of the application for participation in the public bidding,
- deadline for entry into a contract, and
- place, day, and hour of the public bidding.

#### Article 231-b

(1) A person who does not meet the requirements from the announcement cannot participate in the public bidding.

(2) Prior to the commencement of the public bidding, the commission referred to Article 231-a paragraph (1) of this Law shall establish and shall announce the manner and the technical rules of the bidding.

(3) The president of the commission referred to in Article 231-a paragraph (1) of this Law shall manage the work of the Commission and the public bidding.

(4) The commission referred to in Article 231-a paragraph (1) of this Law shall keep an attendance sheet of the present bidders, on which their representatives shall sign by hand.

(5) The commission referred to in paragraph (1) of this Article shall conduct the public bidding pursuant to the announcement for public bidding, in a manner that the participants in the public bidding shall bid the initial amount set out in the announcement for the public bidding.

(6) The deadline for submission of the application for participation in the public bidding cannot be shorter than ten calendar days, nor longer than 30 days as of the day of publication of the announcement up to the day of the submission of the applications.

(7) The application for participation in the public bidding should contain all the data and proofs that are set out in the announcement for the public bidding.

(8) Following the receipt of the applications, the Commission shall determine whether they have been submitted within the determined deadline and whether they are complete in accordance with the requirements in the announcement upon which it shall notify the applicants. It shall deliver a notification to the applicants who have not submitted complete documentation explaining that they shall not participate in the public bidding.

#### Article 231-c

(1) The public bidding shall be held if the participants meet the requirements set in the announcement. The public bidding shall be held even if only a single participant who meets the requirements stated in the publication and who overbids the initial amount has applied.

(2) Following the termination of the public bidding, the Commission shall prepare minutes of the conducted public bidding which shall be delivered to all of the participants in the public bidding. The data on the bidders according to the order of the most favorable bidders shall be particularly entered in the minutes of the course of the public bidding, and the obligation pertaining to the expiry of the deadline within which the most favorable bidder is to conclude the contract of lease is determined.

#### Article 231-d

(1) Where a single bidder who meets the requirements from the announcement applies at the public bidding for lease of premises and overbids the initial amount, the single bidder shall acquire the status of the most favorable bidder, with whom the contract of lease of premises shall be concluded.

(2) If there is no bidder at the public bidding, the public bidding shall be repeated, and the initial amount for the lease of the premises shall be decreased by 5%.

(3) Where the second public bidding is also unsuccessful, the public bidding shall be repeated and the initial amount for the lease of the premises shall be 10% lower than the initial amount published in the announcement of the first public bidding.

#### Article 231-e

(1) Upon the termination of the public bidding procedure, the public healthcare institution shall conclude a contract of lease of immovables with the most favorable bidder within a period of five working days following the payment of the rental fee for the premises. The provisions of the Law on Obligations shall accordingly apply to the contract of lease of immovables.

(2) If the most favorable bidder has not engaged in conduct manifesting its assent to conclude, that is, it does not conclude a contract of lease within a period of 15 days as of the day the most favorable bidder should have concluded the contract, the bidders that are ranked next in line and who have met the requirements and have overbid the initial amount, shall acquire the status of the most favorable bidder and can enter into a contract.

## Article 231-f

- (1) The monetary deposit paid by the most favorable bidder shall be calculated in the reached amount of the rental fee.
- (2) The amount of the monetary deposit which is paid for participation in the public bidding shall equal the amount of the rental fee which is to be paid for the use of the premises under lease in the duration of 12 months.
- (3) The most favorable bidder who does not conclude the contract of lease shall lose the right of return of the monetary deposit.
- (4) The monetary deposit for participation in the public bidding shall be returned in the full amount to the applicant who is not the most favorable bidder for participation in the public bidding, within a period of 15 days as of the day the public bidding has been held.

## Article 231-g

- (1) The participants in the public bidding shall be entitled to file a complaint solely regarding the procedure of the public bidding, within a period of three days as of the day the public bidding has been held, to the Commission deciding upon the complaint by a decision within a period of five days as of the day of receipt of the complaint.
- (2) An appeal against the decision referred to in paragraph (1) of this Article may be filed to the State Commission for Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance.

## Article 231-h

- (1) The contract of lease shall be concluded in a written form and shall particularly include the contracting parties, the subject of the contract, that is, the specific data on the immovable property, and the obligation of the lessee for paying the notary costs.
- (2) The contract which does not contain the elements referred to in paragraph (1) of this Article shall be null and void.
- (3) After concluding the contract, the lessee shall, within a period of 30 days, deliver it to the notary public for solemnization.

## Termination of the license

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### Article 232

- (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

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### 1. Monitoring and promotion of quality of health protection

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#### Determination of the monitoring and the promotion of quality

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##### 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

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##### 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

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#### 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 is more than one healthcare worker with a university degree in the healthcare institution.

## Commission for quality

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### 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

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### 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

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### 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

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### 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.

## 2-a System for strategic planning and management, and balanced assessment of the achievements

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### Article 239-a

(1) A system for strategic planning and management shall be implemented in the public healthcare institutions which shall include monitoring of the public healthcare institutions in view of the strategic goals of the Republic of Macedonia in the field of health with the purpose of providing stability and development of the healthcare system by establishing a Balanced ScoreCard (Balanced ScoreCard), (hereinafter: BSC).

(2) The BSC shall consist of critical success factors and of key performance indicators which shall be determined by the minister of health at a national level, and at the level of a public healthcare institution, for the following areas:

- finances;
- patients;
- clinical focus; and
- development and training.

(3) The minister of health shall determine the BSC at a national level by a program and he/she shall publish it in the "Official Gazette of the Republic of Macedonia".

(4) The minister of health shall determine the BSC at the level of a public healthcare institution on the basis of the BSC at a national level by adopting an order by 1 December in the current year for the following year at the latest.

(5) Key success factors shall be determined for each of the areas referred to in paragraph (2) of this Article, and key performance indicators shall be determined for each key success factor with appropriate target value, weight coefficient and reporting timetable.

(6) Indicators that provide collection of statistical and/or quantitative data required for measuring the indicators shall be set out as key performance indicators.

(7) Minimum, average, or maximum annual target values shall be set out for each key performance indicator that the public healthcare institution should achieve in order to be deemed successful, and that the activity is successfully implemented (hereinafter: target value). Every key performance indicator shall participate in the overall success of the public healthcare institution with a certain percentage (hereinafter: weight coefficient).

#### Article 239-b

(1) The director, that is, the directors of the public healthcare institution shall be responsible for achieving the BSC at the level of the public healthcare institution.

(2) The director, that is, the directors of the public healthcare institution shall be obliged to organize and provide day-to-day collection and processing of the data required for measuring the key performance indicators and entry of these data in the integrated health information system no later than the fifth day of each month for the previous month.

(3) The director, that is, the directors of the public healthcare institution shall be responsible for the accuracy and completeness of the data for measuring the key performance indicators referred to in paragraph (1) of this Article.

(4) The data required for measuring the key performance indicators shall be kept and processed in the integrated health information system in a manner set out by the regulations in the field of health records and by this Law.

#### Article 239-c

(1) The key performance indicators, the annual target values, and the weight coefficient of every key performance indicator shall constitute success indicators that the director should achieve and shall be included in the managerial contract referred to in Article 104 paragraph (3) of this Law.

(2) The director of the public healthcare institution shall be held liable for the failure to achieve the annual target values of the key performance indicators, and he/she shall pay a contractual penalty pursuant to Article 104 paragraph (4) of this Law in the amount equal to the amount for which the salary of the director of the public healthcare institution would be reduced, depending on the percentage of achieved monthly target values which derive from the annual target values of the key performance indicators.

(3) The minister of health shall, by a decision, determine the obligation of the director of the public healthcare institution to pay the contractual penalty referred to in paragraph (2) of this Article in the amount pursuant to paragraphs (7), (8), or (9) of this Article within a period of ten days as of the day of adoption of the decision.

(4) If the director of the public healthcare institution does not pay the contractual penalty within the time period set out in paragraph (3) of this Article, he/she shall be obliged to pay a contractual penalty double the amount of the amount under paragraphs (7), (8), or (9) of this Article within an additional time period of ten days as of the day he/she should have paid the contractual penalty referred to in paragraph (3) of this Article.

(5) The total amount of the contractual penalty that the director of the public healthcare institution is obliged to pay in the course of a month pursuant to paragraph (3) of this Article cannot be higher than Euro 200 in Denar counter value according to the middle exchange rate of the National Bank of the Republic of Macedonia on the day of adoption of the decision referred to in paragraph (3) of this Article.

(6) The total amount of the contractual penalty double the amount of the amount under paragraphs (7), (8), or (9) of this Article that the director of the public healthcare institution is obliged to pay in the course of a month pursuant to paragraph (4) of this Article cannot be higher than Euro 400 in Denar counter value according to the middle exchange rate of the National Bank of the Republic of Macedonia on the day of adoption of the decision referred to in paragraph (3) of this Article.

(7) The director of the public healthcare institution shall be obliged to pay the contractual penalty in the amount of 20% of his/her basic salary in a period of three months if he/she achieves values lower than 80% of the annual target values of the key performance indicators at the level of the public healthcare institution.

(8) The director of the public healthcare institution shall be obliged to pay the contractual penalty in the amount of 10% of his/her basic salary in a period of three months if he/she achieves values from 81% to 85% of the annual target values of the key performance indicators at the level of the public healthcare institution.

(9) The director of the public healthcare institution shall be obliged to pay the contractual penalty in the amount of 5% of his/her basic salary in a period of three months if he/she achieves values from 86% to 90% of the annual target values of the key performance indicators at the level of the public healthcare institution.

(10) The director of the public healthcare institution shall have the right to file an appeal against the decision referred to in paragraph (3) of this Article within a period of eight days as of the day of receipt of the decision to the State Commission for Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance.

(11) The State Commission for Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance shall decide upon the appeal referred to in paragraph (11) of this Article within a period of eight days as of the day of receipt of the appeal.

(12) The appeal referred to in paragraph (11) of this Article shall postpone the enforcement of the decision referred to in paragraph (3) of this Article. Provided that the State Commission for Decision-making in Administrative Procedure and Labor Relation Procedure in Second Instance rejects or denies the appeal and confirms the decision referred to in paragraph (3) of this Article, the contractual penalty referred to in paragraph (2) of this Article shall be paid after the decision referred to in paragraph (3) of this Article becomes final.

( 13 ) The director of the public healthcare institution shall be entitled to salary in the amount of 100% of his/her basic salary if he/she achieves values from 91% to 94% of the annual target values of the key performance indicators at the level of the public healthcare institution.

#### Article 239-d

(1) The top five directors of public healthcare institutions, that is, two directors of public healthcare institutions at tertiary level of health protection, two directors of public healthcare institutions at secondary level of health protection performing hospital activity, and one director of a public healthcare institution at primary level of health protection shall be entitled to one-time monetary reward in the amount of two salaries paid to the director who is rewarded in the last month of the year to which the annual target values refer for exceeding the annual target values of the key performance indicators at the level of a public healthcare institution, for which a decision shall be adopted by the minister of health.

(2) The director of the public healthcare institution shall be entitled to one-time monetary reward in the course of three consequent months in the amount of 5% of his/her basic salary if he/she achieves values from 95% to 97% of the annual target values of the key performance indicators at the level of the public healthcare institution.

(3) The director of the public healthcare institution shall be entitled to one-time monetary reward in the course of three consequent months in the amount of 10% of his/her basic salary if he/she achieves values from 98% to 99% of the annual target values of the key performance indicators at the level of the public healthcare institution.

(4) The director of the public healthcare institution shall be entitled to one-time monetary reward in the course of three consequent months in the amount of 20% of his/her basic salary if he/she achieves 100% of the values of the annual target values of the key performance indicators at the level of the public healthcare institution.

(5) The minister of health shall, by a decision, establish the right to monetary reward referred to in paragraphs (1), (2), (3) and (4) of this Article to the director of the public healthcare institution and its payment within a period of 10 days as of the day of adoption of the decision.

(6) The funds needed for the payment of the monetary reward referred to in paragraphs (1), (2), (3) and (4) of this Article shall be provided from the Budget of the Republic of Macedonia, for which, every year, the Government of the Republic of Macedonia shall adopt a separate program for connecting the salaries of the directors with the criteria and indicators, upon a proposal of the Ministry of Health.

#### Article 239-e

(1) The Ministry of Health shall, four times a year, evaluate the success of the public healthcare institution in achieving the BSC based on the data contained in the integrated health information system and the data delivered by the Fund and the State Sanitary and Health Inspectorate, as well as based on the conducted surveys.

(2) The Ministry of Health shall perform the evaluation referred to in paragraph (1) of this Article as quarterly evaluation in April, July, October, and December in the current year for the previous three months, for which a quarterly report shall be prepared. The Ministry of Health shall publish the quarterly reports on its website no later than the 15th of April, that is, the 15th of July, that is, the 15th of October, that is, the 15th of December.

(3) The Ministry of Health shall prepare an annual report based on the quarterly reports referred to in paragraph (2) of this Article, which shall be published no later than the 15th of January in the current year for the previous year and on the basis of which the minister of health shall adopt a decision imposing the contracting penalty referred to in Article 239-c of this Law or a decision on monetary reward referred to in Article 239-d of this Law no later than the 31st of January in the current year.

(4) The Ministry of Health shall, four times a year, prepare a rank list of the most successful healthcare institutions based on the quarterly report referred to in paragraph (2) of this Article.



(5) The healthcare workers, healthcare co-workers, and other providers of public services in the field of health employed in the public healthcare institution which has been at the first place on the rank list of most successful public healthcare institutions for eight times in the course of two consecutive years shall receive a monetary reward in the amount of 10% of the minimum salary in the Republic of Macedonia pursuant to the regulations that determine the minimum salary in the Republic of Macedonia, in the course of three subsequent months.

(6) The administrative servants and the auxiliary and technical persons employed in the public healthcare institution which has been at the first place on the rank list of most successful public healthcare institutions prepared on the basis of the quarterly reports for eight times in the course of two consecutive years shall receive a monetary reward pursuant to the regulations on administrative servants, as well as the regulations on the public sector employees and the general labor regulations.

(7) The funds needed for the payment of the monetary reward referred to in paragraph (5) of this Article shall be provided from the Budget of the Republic of Macedonia, for which, every year, the Government of the Republic of Macedonia shall adopt a separate program upon a proposal of the Ministry of Health."

#### Article 239-f

(1) The Ministry of Health shall, twice a year, in cooperation with the Agency for Quality and Accreditation of Healthcare Institutions, organize anonymous surveys of patients' satisfaction.

(2) The data from the surveys shall be delivered to the Ministry of Health which shall publicly publish them on its website within a period of three days as of the day of their delivery to the Ministry and shall also submit them to the mass media for publication.

### 3. Accreditation

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#### Definition of accreditation

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##### 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

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##### 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* 25

(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

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### 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; and

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

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### 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

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### 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

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### Article 245

(1) 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.

(2) 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.

(3) 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.

(4) 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.

(5) 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.

(6) 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.

(7) 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.

(8) 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

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#### Ensuring accuracy and reliability of the results of the conducted laboratory tests

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##### Article 245-a

(1) 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.

(2) 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

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### 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

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### 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

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## 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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

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## Health Council

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### 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.

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## Health Ethics Commission

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### 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 healthcare activity, 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.

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## Coordinating body

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## 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.

## National Commission for Diabetes Mellitus

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### Article 248-a

(1) The minister of health shall establish a National Commission for Diabetes Mellitus for the purpose of providing suitable treatment to the patients suffering from diabetes mellitus.

(2) The National Commission for Diabetes Mellitus shall particularly:

- monitor the implementation of the professional instructions for evidence-based medicine in the field of diabetes mellitus in view of the manner of carrying out the healthcare activity pertaining to the treatment and checkups of the patients suffering from diabetes mellitus by the doctors of medicine specialists in internal medicine who prescribe the insulin therapy;
- approve the replacement of the human insulin therapy with insulin analogue therapy and reverse, as well as approve the replacement of the particular insulin analogue therapy with another insulin analogue therapy based on the recommendations deriving from the professional instructions for evidence-based medicine in the field of diabetes mellitus in view of the manner of carrying out the healthcare activity pertaining to the treatment and checkups of the diabetes mellitus; and
- evaluate the insulin therapy of the patients suffering from diabetes mellitus pursuant to their medical documentation and give recommendations for further use of the insulin therapy and the other antidiabetic treatment of the evaluated patients.

(3) The National Commission for Diabetes Mellitus shall have four years term of office and shall be composed of a president and four members selected from among the doctors of medicine who are specialists in internal medicine and doctors of medicine who are specialists in pediatrics, and who are doctors of medicine in the field of endocrinology and diabetology employed or retired in a public healthcare institution which carries out healthcare activity at tertiary level of health protection. The members of the National Commission for Diabetes Mellitus shall have the right to be reselected.

(4) The administrative and technical activities for the needs of the National Commission for Diabetes Mellitus shall be performed by a secretary who shall be appointed by the decision on its establishment from among the employees in the Ministry of Health and he/she shall not be a member of the National Commission for Diabetes Mellitus.

#### Article 248-b

(1) The National Commission for Diabetes Mellitus shall work at working meetings which shall be held at least twice a month. The working meetings shall be held only if all of the members of the National Commission for Diabetes Mellitus are present.

(2) The president of the National Commission for Diabetes Mellitus shall convene the sessions of the National Commission for Diabetes Mellitus, and a session of the Commission can also be convened at the request of the minister of health.

(3) All of the members of the National Commission for Diabetes Mellitus shall be obliged to participate in the work of the National Commission for Diabetes Mellitus by stating their opinion.

(4) Following the discussion held for each case individually, the National Commission for Diabetes Mellitus shall prepare a report that includes the joint findings, conclusions, and recommendations for further treatment, which shall be signed by all of the members of the National Commission for Diabetes Mellitus and which shall constitute an integral part of the patient's medical records.

(5) Records of the presence of the members of the National Commission for Diabetes Mellitus and minutes of the work shall be kept for every meeting. Minutes in a written form and/or in the form of an electronic video or an audio recording shall be kept for the meetings held.

(6) All of the members of the National Commission for Diabetes Mellitus shall be obliged to keep the information presented at the meetings as a business secret.

#### Expert commissions

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##### 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 professional 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 professional associations.

## X-a. E-HEALTHCARE

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### E-healthcare Office

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#### Article 249-a

The E-healthcare Office shall be a state administrative body in the Ministry of Health with the capacity of a legal entity which carries out expert activities of importance for the development and advancement of the integrated health information system, as well as definition of concepts for development of the health policy on the basis of the analyses obtained from the data entered in the national system.

### Organizational structure and civil servants with tasks of specific nature and special performance of the special duties and authorizations

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#### Article 249-b

(1) The organizational structure of the E-healthcare Office (hereinafter: the Office) shall be regulated by the act on internal organization of the Ministry of Health.

(2) The job titles, duties, and number of employees in the Office shall be determined by the act on systematization of jobs.

(3) The civil servants who perform the activities in the field of information and communication technology that serve the integrated health information system shall have their basic salary and the salary supplement for a title increased for 33% resulting from the specific nature of the tasks and special performance of the special duties and authorizations.

### Competence of the E-healthcare Office

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## Article 249-c

(1) The Office shall be responsible for upgrading, optimizing, performing, regulating, maintaining, controlling, educating the healthcare personnel, and analyzing all of the processes and functionalities connected with the integrated health information system, and especially for:

1. upgrading the integrated health information system with new functionalities which are needed and which are used by the healthcare institutions that are part of the network of healthcare institutions, the Ministry of Health, the Health Insurance Fund, the Agency of Medicines, or other entities in the field of health;
2. optimizing and maintaining the program modules and functionalities which are part of the national system;
3. establishing and maintaining a register of healthcare institutions, a register of healthcare workers and healthcare co-workers, a register of healthcare services, a register of patients according to diagnoses of diseases, a register of rare diseases and patients suffering from rare diseases, a register of medical consumables, and other registers for the needs of the healthcare system;
4. establishing and maintaining a single e-health record card of the medical insured persons;
5. designing and maintaining web services for integration and exchange of data with the state administrative bodies, as well as with software solutions which are used in the healthcare institutions that are part of the network of the healthcare institutions;
6. proposing the definition of the duties, authorizations, and responsibilities of the healthcare workers and managerial bodies of the public healthcare institutions in view of the functionalities of the integrated health information system and the lists of scheduled interventions;
7. proposing concepts for development of the health policy to the minister of health on the basis of the analyses obtained from the data entered in the integrated health information system;
8. proposing standards regarding the shortest and longest duration of the specialist and consultative examination per specialist in an out-patient clinic;
9. proposing a work schedule of the employees in the healthcare institutions, as well as a work plan by defining an optimum number of out-patient examinations per doctor or medical apparatus, number of out-patient clinics for particular specialty, as well as other parameters for unobstructed functioning of the integrated healthcare system in view of the lists for scheduling examinations and interventions;
10. controlling the observance of the work standards and protocols in the operation of the healthcare institution in view of the application of the functionalities of the integrated health information system and the electronic list of scheduled examinations and interventions;
11. managing and improving the integrated health information system;
12. defining and updating the code tables which are used for exchanging data in the central base of the integrated health information system with the medical software which is used in

the healthcare institutions in the Republic of Macedonia;

13. optimizing the existing systems for electronic records in the field of health and their integration in a single collaboration system by including all of the competent institutions;

14. conducting training of healthcare workers and healthcare co-workers in healthcare institutions for using the integrated health information system and its functionalities;

15. certifying and approving the use of software solutions which are used in the healthcare institutions that are part of the network of healthcare institutions;

16. preparing analyses and reports which are to be used by the Ministry of Health, the Agency of Medicines, the Government of the Republic of Macedonia, the State Sanitary and Health Inspectorate, the Institute of Public Health, the Agency for Accreditation of Healthcare Institutions, the Health Insurance Fund, and other entities in the field of health;

17. managing the communication center for technical support of all of the users of the integrated health information system; and

18. creating and maintaining a database from the integrated health information system.

(2) The standards and the manner of certification and approval of the use of the software solutions referred to in paragraph (1) point 15 of this Article shall be determined by the minister of health.

(3) Following the adoption of the bylaw referred to in paragraph (2) of this Article, the Ministry of Health shall be obliged to publish it immediately on the website of the Ministry and in the "Official Gazette of the Republic of Macedonia".

(4) The manner of accessing, distributing, issuing, using, keeping, and storing the data from the integrated health information system shall be determined by the minister of health.

(5) A fee shall be paid for using and having insight in the data from the integrated health information system.

(6) As an exception to paragraph (5) of this Article, the Health Insurance Fund of Macedonia shall not pay the fee for using and having insight in the data from the integrated health information system.

(7) The amount of the fee for using and having insight in the data from the integrated health information system shall depend on the actual costs for their preparation, the type of data, the contents of the data, the form of the data (electronic/written), the quantity of the data (the number of identical data issued) and alike.

(8) In the case of an increased number of requests for using the data filed by a single requesting entity, the Office may conclude a contract with the requesting entity regulating the manner of payment.

(9) The amount of the fee for using and having insight in the data from the integrated health information system shall be determined by a tariff adopted by the minister of health.



(10) Following the adoption of the bylaw referred to in paragraph (8) of this Article, the Ministry of Health shall be obliged to publish it immediately on the website of the Ministry and in the "Official Gazette of the Republic of Macedonia".

(11) The Office and the Health Insurance Fund of Macedonia shall exchange the data that they have at their disposal within the framework of their competence, in a manner established by the Ministry of Health and the Health Insurance Fund of Macedonia by means of rules of transfer, that is, sending and receiving data.

## Financing the activity of the Office

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### Article 249-d

(1) The funds for financing the Office shall be provided from the Budget of the Republic of Macedonia.

(2) The Office may earn its own incomes, incomes from donations, and from other sources determined by this Law.

## Management of the Office

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### Article 249-e

(1) The Office shall be managed by a director.

(2) The director of the Office shall be appointed and dismissed by the Government of the Republic of Macedonia on a proposal of the minister of health for a four-year term of office.

(3) The Office shall publish a public announcement for appointment of a director in at least three daily newspapers that are printed on the whole territory of the Republic of Macedonia, one of which is a newspaper printed in a language spoken by at least 20% of the citizens who speak an official language other than the Macedonian. 26

### Article 249-f

(1) Director of the Office may be appointed a person who:

1. is a citizen of the Republic of Macedonia;
2. at the moment of appointment, is not issued a penalty or misdemeanor sanction banning him/her from exercising a profession, business or office by an effective court ruling;
3. has completed a higher education (VII/1) or at least 240 ECTS in the field of natural sciences and mathematics or information technology studies;
4. has at least five years of experience in managing systems with larger number of users, out of which three years in managing projects in the field of health; and
5. holds one of the following internationally recognized certificates for active knowledge of the 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.

(2) The director of the Office shall be accountable for his/her work and for the work of the Office to the Government of the Republic of Macedonia and the minister of health.

(3) The director of the Office shall adopt an annual work program of the Office and he/she shall organize its implementation.

(4) The director shall submit an annual report on his/her work and the work of the Office to the minister of health for adoption, and if needed also to the Government of the Republic of Macedonia for information.

(5) The director shall submit the annual report on the work of the Office to the Ministry of Health for adoption by 31 March in the current year for the preceding year at the latest.

#### Article 249-g

(1) The Government shall dismiss the director of the Office if he/she:

- does not act pursuant to the law and the general acts of the Office,
- inflicts damage to the Office by his/her negligent and incorrect work,
- neglects or does not meet the obligations and therefore more serious disturbances occur or might occur in the performance of the Office's activity, and
- works contrary to the law.

(2) The term of office of the director of the Office shall terminate in the following cases:

- at his/her 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, and
- if due to his/her age, the employment contract or the contract for continuation of the employment terminates, pursuant to the regulations in the field of labor relations.

### Performing expert activities within the competence of the Office

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#### Article 249-h

(1) The director may create expert teams consisting of external scientific experts in order to perform the expert activities within the competence of the Office.

(2) The composition and the number of members of the expert teams shall be determined by the director of the Office by a decision.

(3) The director may, by means of a written authorization, transfer certain competences to the managerial persons in the Office.

(4) The professional, administrative and technical, auxiliary and other activities shall be performed by the persons employed in the professional services of the Office.

## XI. CHAMBER ASSOCIATION

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### Chambers

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#### 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

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#### 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

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### 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

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### 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

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## 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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 professional 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 professional supervision of the work of the healthcare workers on the basis of an annual plan for professional 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 professional 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

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### 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

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### 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

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### 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 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

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### 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

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### 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

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Determination of the time and the reason of death and prohibition of burial prior to conducting an examination or autopsy

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### 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

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### 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

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### 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

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### 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 professional 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

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### 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

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### 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

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## 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 professional determination of the time and reasons of death

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### 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

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### 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 medication 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

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### 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

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### Prohibited and allowed marketing

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#### 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 professional articles in professional magazines, books and publications, intended for informing the healthcare institutions, that is, the healthcare workers.

(7) The public healthcare institutions shall have the right to advertise the health services they provide to foreigners that cover the costs for treatment by themselves in the mass media, in other media for promotional and advertising messages in the Republic of Macedonia and abroad, as well as on Internet.

## Marketing prohibition by a decision

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### 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

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### 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.

(4) Abolished 27

## Marking the facility where the healthcare activity is performed

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### 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

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### Determination of the tasks for providing health protection in states of emergency and crises

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#### 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

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#### Article 282

The Ministry of Health and the healthcare institutions shall be obliged to provide funds for stockpile of medications 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

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#### 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

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#### 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

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#### 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

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### 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

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### 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

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### 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 28

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## Compensation paid upon production and import of tobacco products

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Article 289

*Deleted 29*

## Reimbursement of the compensation

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Article 290

*Deleted 30*

## Manner and procedure of establishing, calculating and paying

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Article 291

*Deleted 31*

## Records of persons obliged to pay compensations

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Article 292

*Deleted 32*

## Time barring of the obligation for payment

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Article 293

*Deleted 33*

## XVI. SUPERVISION

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### Definition of supervision

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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

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### 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* 34

(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

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### 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

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### 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

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### 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* 35

(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

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### 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

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### 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

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### 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

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### 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

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### 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

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### 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

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### Rendering health services without a license for work

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#### 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. 36

### Disclosure of a business secret

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#### 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.

### Entry of incorrect data on the number, type, and scope of healthcare services in the integrated health information system

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#### Article 304-c

Whosoever enters incorrect data on the number, type, and scope of healthcare services, enters data on the healthcare services that have not been performed, or does not enter data on the healthcare services that have been performed in the integrated health information system shall be held criminally liable and shall be fined or sentenced to imprisonment of up to one year." 37

### An assault on a healthcare worker and healthcare co-worker when performing a healthcare activity

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#### Article 304-d

(1) Whosoever assaults or makes a serious threat to assault a healthcare worker and a healthcare co-worker when performing a healthcare activity as an official duty and when rendering healthcare services shall be fined or shall be sentenced to imprisonment of up to three years.

(2) If in the commission of the action referred to in paragraph (1) of this Article, the offender harasses or insults the healthcare worker and/or the healthcare co-worker, or inflicts a bodily harm on him/her by using a weapon or another dangerous instrument, he/she shall be sentenced to imprisonment from six months up to five years.

(3) If in the commission of the action referred to in paragraph (1) of this Article, the healthcare worker and/or the healthcare co-worker has been inflicted a grievous bodily harm, the offender shall be sentenced to imprisonment from one to ten years.

(4) The offender referred to in paragraphs (1) and (2) of this Law has been provoked by an illegal or harsh behavior of the healthcare worker and/or the healthcare co-worker, he/she can be acquitted.

## XVII. MISDEMEANOR PROVISIONS

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### Article 305

(1) Fine in the amount of Euro 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 30% of the determined fine for the legal entity shall be also imposed on the responsible person in the legal entity for the misdemeanors referred to in paragraph (1) of this Article.

(3) Fine in the amount of Euro 600 to 900 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) 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 double amount of the determined amount in paragraph (2) of this Article, 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.

(5) 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.

(6) 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 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 medications 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 30% of the determined fine for the legal entity shall be also imposed on the responsible person in the legal entity for the misdemeanors 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 a misdemeanor sanction prohibition on performing a healthcare activity for a period of three months to one year.

## Article 307

(1) Fine in the amount of Euro 5.000 in Denar counter-value shall be imposed for a misdemeanor on a legal entity if it:

- 1) as a healthcare institution in the network 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 professional 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 a professional examination 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 professional 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 30% of the determined fine for the legal entity shall be also imposed on the responsible person in the legal entity for the misdemeanors referred to in paragraph (1) of this Article.

(3) Fine in the amount of Euro 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 30% of the determined fine for the legal entity shall be also 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 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 30% of the determined fine for the legal entity shall be also imposed on the responsible person in the legal entity for the misdemeanors 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 in which he/she is having the specialty, that is, sub-specialty training 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 in which the resident is having the specialty, that is, sub-specialty training 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 medications, 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 medications, 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 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 30% of the determined fine for the legal entity shall be also imposed on the responsible person in the legal entity for the misdemeanor referred to in paragraph (4) of this Article.
- (6) Fine in the amount of Euro 1.200 to 1.800 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 available appointments 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 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 30% of the determined fine for the legal entity shall be also imposed on the responsible person in the legal entity for the misdemeanor referred to in paragraph (11) of this Article.

(13) Fine in the amount of Euro 3.000 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 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 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 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 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 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 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 30% of the determined fine for the legal entity shall be also imposed on the responsible person in the legal entity for the misdemeanor referred to in paragraph (25) of this Article.

(27) Fine in the amount of Euro 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 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 by issuing an on-the-spot payment order 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 medications and medical equipment for which he/she is directly responsible.

(2) The inspector shall issue the healthcare worker an on-the-spot payment order for the actions referred to in paragraph (1) of this Article.

(3) The perpetrator shall be obliged to pay the fine in the determined amount within a period of eight days as of the day of delivery of the on-the-spot payment order.

(4) If the perpetrator does not pay the fine referred to in paragraph (1) of this article voluntarily, the on-the-spot payment order shall have the force of enforcement document and the inspector shall deliver it to the body competent for forced enforcement for the purpose of its enforcing.

#### Article 313-a

(1) Fine in the amount of Euro 5.000 in Denar counter-value shall be imposed for a misdemeanor on a legal entity if:

1) it does not enable a healthcare worker, that is, a healthcare co-worker employed in a healthcare institution in the network to work, on the basis of a travel order from the Ministry of Health for a period of three working days during one month, that is, five working days at the most during one month by means of a written consent from the healthcare worker, that is, the healthcare co-worker, in another healthcare institution in the network of healthcare institutions in which there is a need of carrying out the duties by the healthcare worker, that is, the healthcare co-worker pursuant to Article 28 paragraphs (4) and (5) of this Law, and the healthcare institution in the network of healthcare institutions where he/she is sent to work by means of a travel order does not pay, in accordance with Article 28 paragraph (6) of this Law, to the healthcare worker, that is, the healthcare co-worker the travel and daily expenses in accordance with law and a collective agreement for the period he/she has been sent;

2) the medical director of the healthcare institution in the network at secondary and tertiary level of health protection does not determine in advance a calendar of activities not earlier than the tenth day of the current month for the following month for each healthcare worker rendering specialist and consultative services in the healthcare institution and does not determine a calendar of available appointments for using the medical equipment by means of which the healthcare institution renders specialist and consultative services pursuant to Article 39-a paragraph (2) of this Law;

3) the healthcare worker who renders services in the healthcare institutions in the network at secondary and tertiary level of health protection does not determine in advance a calendar of activities not earlier than the fifth day of the current month for the following month and does not submit it to the director of the healthcare institution pursuant to Article 39-a paragraph (4) of this Law;

4) the healthcare worker who renders specialist and consultative services in the healthcare institutions in the network at secondary and tertiary level of health protection does not refer the patients who he/she has examined, that is, who he/she has made an intervention on at secondary and tertiary level of health protection for additional specialist and

consultative services through the electronic list of scheduled examinations and interventions for the purpose of diagnosing and treating the diseases and the injuries and rehabilitating, and if he/she does not issue an interspecialist referral, a specialist and sub-specialist referral, a referral for radio diagnostics and a referral for laboratory services pursuant to Article 39-a paragraph (5) of this Law;

5) the healthcare worker who renders specialist and consultative services in the healthcare institutions in the network at secondary and tertiary level of health protection does not refer the patients who he/she has examined, that is, who he/she has made an intervention on to a control specialist and consultative service through the electronic list of scheduled examinations and interventions and does not issue a control referral pursuant to Article 39-a paragraph (6) of this Law;

6) the healthcare worker who renders specialist and consultative services in the healthcare institutions in the network at secondary and tertiary level of health protection does not refer the patients who he/she has examined, that is, who he/she has made an intervention on at secondary and tertiary level of health protection to a hospital treatment in the institution where he/she works or to a surgical intervention which he/she is making and does not issue a hospital referral and/or hospital referral for surgical interventions pursuant to Article 39-a paragraph (7) of this Law.

7) the healthcare worker who performs surgical interventions in the healthcare institutions in the network at secondary and tertiary level of health protection has not scheduled appointments for performing elective surgical interventions in the calendar of activities pursuant to Article 39-a paragraph (9) of this Law;

8) the list containing a time schedule of patients who should undergo a surgical intervention (surgery program) has not been prepared pursuant to Article 39-a paragraph (10) of this Law based on the appointments for performing elective surgical interventions referred to in Article 39-a paragraph (9) of this Law and the issued hospital referrals for surgical interventions referred to in Article 39-a paragraph (7) of this Law;

9) the list containing a time schedule of patients who should undergo a surgical intervention (surgery program) pursuant to Article 39-a paragraph (10) of this Law has not been entered in the electronic lists of scheduled examinations and interventions;

10) the surgery program is not approved, that is, has not been approved by the professional collegium of the healthcare institution where the surgical intervention is performed in the current week for the next week pursuant to Article 39-a paragraph (10) of this Law;

11) every change in the surgery program is not entered, that is, has not been entered in the electronic list of scheduled examinations and interventions by stating the reasons due to which the change is made and it pursuant to Article 39-a paragraph (10) of this Law;

12) the healthcare institution has not notifies, that is, does not notify the patients immediately, and within a period of 24 hours at the latest as of the occurrence of the change in the surgery program pursuant to Article 39-a paragraph (10) of this Law;

13) the healthcare worker who renders specialist and consultative services does not perform the examination at the time of the appointment scheduled through the electronic

list of scheduled examinations and interventions pursuant to Article 39-b paragraph (1) of this Law or postpones the start of the examination, that is, the intervention for which there are no objective and justifiable reasons pursuant to Article 39-b paragraph (3) of this Law;

14) the healthcare worker who renders specialist and consultative services, who has made an unfounded and unjustified referral of patients to secondary and tertiary level of health protection for using medical equipment in the cases referred to in Article 39-l paragraph (3) of this Law (refers patients for specialist and consultative services by using medical equipment contrary to the professional instructions for evidence-based medicine referred to in Article 27 paragraph (1) of this Law and the protocols referred to in Article 27 paragraph (4) of this Law, and refers the patients to diagnostic procedures for radiological diagnostics with computer tomography and magnetic resonance in accordance with the professional instructions for evidence-based medicine referred to in Article 27 paragraph (1) of this Law and the protocols referred to in Article 27 paragraph (4) of this Law, but absence of a disease and/or injury has been established by the conducted examinations in 20% of the total number of referrals for using medical equipment in the course of the preceding year, unless the patient is referred to diagnostic procedures for radiological diagnostics with a computer tomograph and magnetic resonance for the purpose of proving the absence of a disease and/or injury in accordance with the professional instructions for evidence-based medicine) does not attend training in the duration of 20 hours for the professional instructions for evidence-based medicine referred to in Article 27 paragraph (1) of this Law and the protocols referred to in Article 27 paragraph (4) of this Law and training for familiarization with the features of the medical equipment, its use, and the harmful consequences arising from the unfounded and excessive use of the medical equipment pursuant to Article 39-l paragraph (5) of this Law;

15) the people that keep, publish, and update the electronic list of scheduled examinations and interventions do not enter the data that a particular medical equipment is malfunctioning immediately after the occurrence of the malfunction pursuant to Article 92-c paragraph (7) of this Law;

16) it does not introduce regular record keeping of all basic and auxiliary medical materials spent per patient, referral, and healthcare worker, that is, healthcare co-worker, and mandatory records keeping of the medical material supplies in the main depot and in all the ancillary depots for medications pursuant to Article 92-d paragraph (4) of this Law;

17) the higher education institution and the healthcare institution do not allocate and use the funds that they receive for the carrying out of the specialty, that is, sub-specialty training in a manner and in the amount pursuant to Article 140 paragraphs (4), (5), (6), (7), (8) and (9) of this Law;

18) the higher education institution where the specialty, that is, sub-specialty training is delivered and the public healthcare institution where the healthcare workers, that is, the healthcare co-workers are enrolled for specialty, that is, sub-specialty training pursuant to Article 150 of this Law calculates and/or charges the compensation for the public healthcare institution for the material costs incurring from the specialty, that is, subspecialty training

and for the promotion and development of the healthcare services in the public healthcare institution contrary to Article 140 paragraph (9) of this Law;

19) the data referred to in Article 144-a paragraph (4) of this Law have not been entered in the resident booklet and the data referred to in Article 144-a paragraph (5) of this Law have not been entered in the book of records of the completed procedures and interventions;

20) the resident booklet referred to in Article 144-a paragraph (4) of this Law and the book of records of the completed procedures and interventions referred to in Article 144-a paragraph (5) of this Law have not been correctly and completely filled, if incorrect, false, and incomplete data have been entered, as well as if the curriculum of the residency has not been delivered at all or it has been delivered partially, that is, the procedures and interventions completed in the course of the residency entered in the book of records of the completed procedures and interventions do not entirely correspond to the contents of the residency set out in the curriculum for specialty training of the healthcare workers and health co-workers with a university degree pursuant to Article 144-a paragraph (6) of this Law;

21) the resident, for the purpose of gaining practical professional knowledge and scientific findings, does not spend eight hours a day in the healthcare institution in which, under the specialty curriculum, the general part, that is, the specialty part of the residency is delivered pursuant to Article 144-c paragraphs (1) and (4) of this Law that is, the resident does not spend time on professional development during on-duty work with which continuous 24-hour healthcare activity in the healthcare institution in which the general, that is, specialty module is delivered is provided once each week, that is, four times in the course of each month pursuant to Article 144-c paragraphs (2) and (5) of this Law, and the healthcare institution does not enable him/her to exercise the right to 24-hour rest in the course of the next day following the day of on-duty work pursuant to Article 144-c paragraphs (3) and (6) of this Law;

22) the resident does not record his/her presence via the system for records of the working hours in the healthcare institution in which the module is delivered, pursuant to Article 144-c paragraph (11) of this Law;

23) the higher education institution in which the specialty training is delivered does not provide at least one premises for taking the examination, specially equipped for taking a professional examination with material-technical, and IT equipment, internet connection, and equipment for recording the examination pursuant to Article 144-l paragraph (2) of this Law;

24) the resident does not meet the obligations referred to in Article 144-d paragraphs (1) and (3) of this Law for participation in a daily and morning meeting, Article 144-e paragraph (1) of this Law for mandatory trainings, Article 144-f paragraphs (1) and (3) of this Law for learning foreign languages, Article 144-h paragraph (2) of this Article regarding the obligations of the resident in the course of the overall duration of the specialty training, Article 144-i paragraphs (1), (2) and (5) of this Law regarding the obligations of the resident in the course of the first and second year of the specialty training, Article 144-m paragraphs



(1), (2), (5), (7), (8), (13) and (14) of this Law for practical training at a general or specialized hospital, at an emergency medical care service or at a medical center, doing a daily visiting round and attending an autopsy, and Article 144-o paragraphs (1), (4), (5) and (6) of this Law for specialty training in surgery and internal medicine;

25) the healthcare institution in which the specialty training is delivered does not provide learning of the English language to the residents in cooperation with the higher education institutions in the field of philology or in cooperation with other institutions in the field of education, where the teaching is delivered by persons who have at least ten years of experience in the profession, as well as if it does not conclude a contract for testing the residents with an official European tester, a member of ALTE, and the Ministry of Health does not organize learning of the foreign languages which, pursuant to Article 144-f paragraph (1) of this Law, are learnt as a second language, pursuant to Article 144-f paragraph (8) of this Article,;

26) the healthcare institution in which the specialty training from all of the specialty branches for the residents is delivered does not organize and deliver at least 250 hours of theory classes in total from the corresponding specialty branch, out of which at least 15% of the total number of hours from the envisaged theory classes shall be in the field of scientific-research work, adopting a clinical decision, communication skills, public health, ability of acquiring and transferring knowledge, ethics, and regulations and promotion of the health in the course of the overall duration of the specialty training pursuant to Article 144-h paragraphs (2) and (3) of this Law;

27) the authorized healthcare institution in which the specialty part of the residency of the resident is delivered does not deliver to the Ministry of Health a draft schedule of the senior residents in the general and special hospitals pursuant to Article 144-m paragraph (3) of this Law;

28) the healthcare institution which has sent the senior resident to specialty training has not compensated the senior resident the travel costs in the amount of a bus or railway ticket for the period spent in a general or specialized hospital pursuant to Article 144-m paragraph (4) of this Law;

29) the higher education institution in which the specialty training is delivered does not submit to the Ministry of Health a proposal for the time schedule of the modules in the course of the last year of the specialty training when the senior resident mandatorily delivers modules in the emergency medical care service, hospital or medical center with a head office in the municipality in which the head office of the public healthcare institution which has sent the healthcare worker or the healthcare co-worker to specialty training is located, and in an emergency center or clinical hospital pursuant to Article 144-m paragraph (15) of this Law;

30) the public healthcare institution does not approve the request, pursuant to Article 150-a paragraph (2) of this Law, of the healthcare workers and the healthcare co-workers employed in a public healthcare institution and enrolled in the specialty, that is, sub-specialty training pursuant to Article 150 of this Law for continuation of the specialty, that is,

sub-specialty training at the cost of the healthcare institution in which they are employed by adopting a decision in the cases where the conditions referred to in Article 150-a paragraph (1) of this Article are met;

31) the public healthcare institution which has approved the request referred to in Article 150-a paragraph (1) of this Law does not continue to cover the costs for the carrying out of the specialty, that is, sub-specialty training pursuant to Article 150-a paragraph (3) of this Law;

32) the public healthcare institution which performs a specialist and consultative, and hospital activity, and which employs the healthcare workers, that is, the healthcare co-workers enrolled in specialty, that is, sub-specialty training pursuant to Article 150 of this Law, does not continue to compensate their costs for the specialty, that is, sub-specialty training as of the day of concluding the employment contract in the cases where the conditions referred to in Article 150-b paragraph (1) of this Law are met;

33) it does not terminate the employment contract of the healthcare workers, that is, the healthcare co-workers enrolled in specialty, that is, sub-specialty training pursuant to Article 150 of this Law, who have been employed in a public healthcare institution which performs a specialist and consultative, and hospital activity pursuant to Article 150-b paragraph (2) of this Law, because the healthcare worker, that is, the healthcare co-worker has not conclude a specialty, that is, sub-specialty training contract with the public healthcare institution in which he/she is employed;

34) the healthcare worker, that is, the healthcare co-worker does not wear, during the working hours, at his/her workplace, a tag in the form of a card in a visible place containing a photo of the healthcare worker, that is, the healthcare co-worker, his/her name, the position, and the healthcare institution where he/she works pursuant to Article 169 paragraph (1) of this Law;

35) the surgical interventions in the healthcare institutions are performed contrary to the protocol for safe surgery which includes checking the actions taken pursuant to the surgical safety checklist before, during, and after the completion of the surgical intervention, for the purpose of lowering the possibility of a mistake when performing the surgical intervention (Article 226-j paragraph (1) of this Law);

36) the healthcare treatment of the patients suffering from malignant diseases which covers diagnostics and treatment of malignant diseases is performed contrary to the clinical pathway by which the obtaining of a priority status of the patients suffering from malignant diseases in view of the rendering healthcare services, the longest period of time as of the time of scheduling up to the time of the examinations and interventions, and the mandatory examinations and interventions of the patients suffering from malignant diseases is particularly established (Article 226-k paragraph (1) of this Law);

(2) Fine in the amount of 30% of the determined fine for the legal entity shall be also imposed on the responsible person in the legal entity for the misdemeanors referred to in paragraph (1) of this Article.

(3) Fine in the double amount of the amount determined in paragraph (2) of this Article shall be imposed on the responsible person in the legal entity if the misdemeanor referred to in paragraph (1) of this Article is repeated.

(4) Fine in the amount of Euro 500 to 1.000 in Denar counter-value shall be imposed on the responsible person in the legal entity if:

- 1) it does not conduct a procedure for determining disciplinary liability pursuant to Article 28 paragraph (7) of this Law of the healthcare worker, that is, the healthcare co-worker referred to in Article 28 paragraphs (4) and (5) of this Law within a period of five days as of the day the healthcare worker, that is, the healthcare co-worker referred to in Article 28 paragraphs (4) and (5) of this Law failed to report to work, that is, failed to execute the duties in the other healthcare institution based on a travel order from the Ministry of Health;
- 2) it does not ensure that each patient is informed of his/her right referred to in Article 39-a paragraph (15) of this Law by a written notification which is displayed at the entrance of the healthcare institution, in an easily visible and accessible place (Article 39-a paragraph (12)).
- 3) it does not organize printing of the notification in a written form in sufficient number of copies that the examination, that is, intervention has not been performed within the appointment scheduled via the electronic list of scheduled examinations and interventions or that there has been a delay in the performance of the examination, that is, intervention which is contrary to Article 39-b paragraphs (2) and (3) of this Law which is placed at the entrance of the healthcare institution, in an easily visible and accessible place pursuant to Article 39-b paragraph (6) of this Law;
- 4) it does not display a written notification in a visible place and/or it does not designate a person employed in the public healthcare institution pursuant to Article 39-b paragraphs (16) and (17) of this Law, that is, it does not send a notification through the integrated health information system pursuant to Article 39-b paragraph (16) of this Law;
- 5) it does not conduct a procedure for determining disciplinary liability of the healthcare worker who renders specialist and consultative services due to the fact that he/she does not attend the training pursuant to Article 39-l paragraph (5) of this Law (Article 39-l paragraph (7));
- 6) it does not submit a written notification to the Ministry of Health on each malfunction of the medical equipment within a period of no more than 24 hours as of the time the malfunction has occurred pursuant to Article 92-c paragraph (5) of this Law, and it does not ensure entry of data that the particular medical equipment is malfunctioning immediately after the occurrence of the malfunction in the electronic list of scheduled examinations and interventions pursuant to Article 92-c paragraph (6) of this Law.
- 7) it does not conduct a disciplinary procedure against the persons that keep, publish, and update the electronic list of scheduled examinations and interventions and who have not entered the data that a particular medical equipment is malfunctioning immediately after the occurrence of the malfunction pursuant to Article 92-c paragraph (7) of this Law (Article 186 paragraph (1) point 27) of this Law);
- 8) it does not enter in the mandatory records of the medical material supplies in the main

depot and in all the ancillary depots for medications for the purpose of having exact information about the supplies of medications together with their expiration date, destruction of the medications with passed expiration date, timely provision of new supplies and protection of patients from taking inadequate medications, particularly the data on the EAN (European Article Number) code of the medication, production date of the medication, and expiration date of the medication pursuant to Article 92-d paragraph (5) of this Law;

9) it does not ensure and organize in the financial accounting system all material documents to be given an account and to be recorded and a debit entry to be made in a financial order, and in particular the receipts of the suppliers and the transfer documents from the main depot, the internal receipts on the grounds of the transfer documents and the requisition forms/lists of the medical materials spent per patients and healthcare workers, that is, healthcare co-workers from the ancillary depots, price leveling documents, the return receipts, incoming and outgoing invoices, and the statements of the budgetary and the personal account pursuant to Article 92-d paragraph (7) of this Law;

10) it does not act upon orders, instructions, plans and programs adopted by the minister of health, which order or prohibit acting in a particular situation which is of general importance for the implementation of the laws and bylaws, which prescribe the manner of acting when implementing particular provisions of the laws and bylaws, that is, which determine and elaborate particular issues regarding the implementation of the laws and bylaws for which setting deadlines and time-schedule for their implementation is required pursuant to Article 104 paragraph (6) of this Law;

11) the public healthcare institution which sends healthcare workers and healthcare co-workers to specialty, that is, sub-specialty training does not conclude a contract with the higher education institution where the specialty, that is, sub-specialty training is delivered, that is, the higher education institution where the specialty, that is, sub-specialty training is delivered does not conclude a contract with the public healthcare institutions which sends healthcare workers and healthcare co-workers to specialty and sub-specialty training pursuant to Article 140 paragraph (4) of this Law within a month as of the day of adoption of the specialty, that is, sub-specialty curriculum, and before the payment of the funds from the compensation;

12) the higher education institution does not conclude a contract with the public healthcare institutions where particular skills under the specialty, that is, sub-specialty training curriculum are being acquired and gained which envisages distribution and payment of 50% of the funds for compensation for each individual resident, that is, sub-specialty trainee earmarked for the delivery of his/her specialty, that is, sub-specialty training pursuant to Article 140 paragraph (5) of this Law within a period of two months as of the day of adoption of the specialties, that is, sub-specialties' curriculum, and before the payment of the funds from the compensation referred to in Article 140 paragraph (2) of this Law, pursuant to Article 140 paragraph (5) of this Law (Article 140 paragraph (6) of this Law);

13) the higher education institution where the specialty and sub-specialty training is

delivered does not conclude a contract with the mentor for payment of the remuneration in the amount of 90% of the funds that the higher education institution receives for each resident, that is, sub-specialty trainee who is under his/her mentorship, pursuant to Article 140 paragraph (7) of this Law;

14) the public healthcare institution where particular skills under the specialty, that is, sub-specialty training curriculum are acquired and gained does not conclude a contract with the educator for payment of the remuneration in the amount of 60% of the funds that the higher education institution receives for each individual resident, that is, sub-specialty trainee who is under the guidance of that particular educator, pursuant to Article 140 paragraph (8) of this Law;

15) the director of the healthcare institution in which the module is delivered does not undertake appropriate measures pursuant to Article 144-m paragraph (9) of this Law in the case where the senior resident has delivered a notification to him/her stating that a particular patient is not being treated in line with the instructions for evidence-based medicine;

16) the director of the healthcare institution in which the module is delivered does not determine and does not publish publicly a time schedule of the daily visiting rounds for each senior resident separately pursuant to Article 144-m paragraph (10) of this Law;

17) it does not organize and ensure that the healthcare worker, that is, the healthcare co-worker wears a tag in a visible place during the working hours, at his/her workplace, in the form of a card containing a photo of the healthcare worker, that is, the healthcare co-worker, the name, the position and the healthcare institution where he/she works pursuant to Article 169 paragraph (2) of this Law;

18) it does not initiate a disciplinary procedure against the healthcare worker, that is, the healthcare co-worker who does not wear the tag in the form of a card containing a photo of the healthcare worker, that is, the healthcare co-worker, the name, the position and the healthcare institution where he/she works within a period of seven days as of the day it became familiar with the reason for initiating a disciplinary procedure pursuant to Article 169 paragraph (2) of this Law;

19) it does not give its respond to the complainant referred to in Article 193-a paragraph (1) of this Law regarding the justification of the complaint within a period of 15 days as of the receipt of the complaint pursuant to Article 193-a paragraph (6) of this Law;

20) it does not establish a commission for conducting a disciplinary procedure for a disciplinary offense, it does not notify the complainant referred to in Article 193-a paragraph (1) of this Law that a commission has been established within a period of three days as of the establishment of the commission and/or it does not adopt a decision imposing a disciplinary measure for a disciplinary offense within a period of 15 days as of the day of initiation of the procedure, that is, it does not deliver a copy of the decision imposing a disciplinary measure for a disciplinary offense within a period of three days as of the day of the adoption of the decision pursuant to Article 193-a paragraphs (8) and (9) of this Law;

21) it does not conduct a disciplinary procedure for a disciplinary offense against the

healthcare worker pursuant to Article 193-a paragraph (13) of this Law;

22) it is established that the director, that is, the directors of the public healthcare institution do not organize and provide day-to-day collection and processing of the data required for measuring the key performance indicators and entry of these data in the integrated health information system no later than the fifth day of each month for the previous month pursuant to Article 239-b paragraph (2) of this Law or that incorrect and/or false data required for measuring the key performance indicators have been entered (Article 239-b paragraph (3) of this Law);

23) the data required for measuring the key performance indicators are kept and processed in the integrated health information system contrary to the manner set out by the regulations in the field of health records and by this Law (Article 239-b paragraph (4) of this Law).

(5) Fine in the double amount of determined amount of paragraph (4) of this Article shall be imposed on the responsible person in the legal entity if the misdemeanor referred to in paragraph (4) of this Article is repeated.

(6) 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 completed higher education, that is, a healthcare co-worker with a completed higher education if:

1) he/she does not determine in advance a calendar of activities not earlier than the fifth day of the current month for the following month and does not submit it to the director of the healthcare institution pursuant to Article 39-a paragraph (4) of this Law;

2) he/she does not refer the patients who he/she has examined, that is, who he/she has made an intervention on at secondary and tertiary level of health protection to additional specialist and consultative services through the electronic list of scheduled examinations and interventions for the purpose of diagnosing and treating the diseases and the injuries and rehabilitating, and he/she does not issue an interspecialist referral, a specialist and sub-specialist referral, a referral for radio diagnostics and a referral for laboratory services pursuant to Article 39-a paragraph (5) of this Law;

3) he/she does not refer the patients who he/she has examined, that is, who he/she has made an intervention on to a control specialist and consultative service through the electronic list of scheduled examinations and interventions and he/she does not issue a control referral pursuant to Article 39-a paragraph (6) of this Law;

4) he/she does not refer the patients who he/she has examined, that is, who he/she has made an intervention on at secondary and tertiary level of health protection to a hospital treatment in the institution where he/she works or to a surgical intervention which he/she is making and he/she does not issue a hospital referral and/or a hospital referral for surgical interventions pursuant to Article 39-a paragraph (7) of this Law.

5) he/she does not schedule appointments for performing elective surgical intervention in the calendar of activities pursuant to Article 39-a paragraph (9) of this Law;

6) he/she does not perform the examination within the appointment scheduled through the

electronic list of scheduled examinations and interventions pursuant to Article 39-b paragraph (1) of this Law;

7) he/she has made an unfounded and unjustified referral of the patients to secondary and tertiary level of health protection for using medical equipment contrary to the professional instructions for evidence-based medicine referred to in Article 27 paragraph (1) of this Law and the protocols referred to in Article 27 paragraph (4) of this Law (Article 39-b of this Law), and/or he/she has made an unfounded and unjustified referral of the patients to diagnostic procedures for radiological diagnostics with a computer tomography and magnetic resonance in accordance with the professional instructions for evidence-based medicine referred to in Article 27 paragraph (1) of this Law and the protocols referred to in Article 27 paragraph (4) of this Law, but absence of a disease and/or injury has been established by the conducted examinations in 20% of the total number of referrals for using medical equipment in the course of the preceding year, unless the patient is referred to diagnostic procedures for radiological diagnostics with a computer tomography and magnetic resonance for the purpose of proving the absence of a disease and/or injury in accordance with the professional instructions for evidence-based medicine (Article 39-l paragraph (3) of this Law);

8) he/she, despite the training attended pursuant to Article 39-l paragraph (5) of this Article and despite the imposed disciplinary measure for disciplinary offense referred to in Article 39-l paragraph (8) of this Law, continues to make unfounded and unjustified referral of patients to secondary and tertiary level of health protection for using medical equipment contrary to the professional instructions for evidence-based medicine referred to in Article 27 paragraph (1) of this Law and the protocols referred to in Article 27 paragraph (4) of this Law, and/or continues the practice of having absence of a disease and/or injury in 20% of the total number of referrals for using medical equipment in the course of the preceding year which is established by the conducted examinations, unless the patient is referred to diagnostic procedures for radiological diagnostics with a computer tomography and magnetic resonance for the purpose of proving the absence of a disease and/or injury in accordance with the professional instructions for evidence-based medicine;

9) the resident, for the purpose of gaining practical professional knowledge and scientific findings, does not spend eight hours a day in the healthcare institution in which, under the specialty curriculum, the general, that is, the specialty part of the residency is delivered pursuant to Article 144-c paragraphs (1) and (4) of this Law, that is, the resident does not spend time on professional development during on-duty work by which continuous 24-hour healthcare activity in the healthcare institution in which the general, that is, specialty module is delivered is provided once each week, that is, four times in the course of each month pursuant to Article 144-c paragraphs (2) and (5) of this Law, and the public healthcare institution does not enable him/her to exercise the right to 24-hour rest during the day following the day of on-duty work pursuant to Article 144-c paragraphs (3) and (6) of this Law;

10) the mentor and the educator do not verify with their signature and seal pursuant to

Article 144-a paragraph (8) of this Article or verify a resident booklet referred to in paragraph (4) of this Article and a book of records of the completed procedures and interventions referred to in paragraph (5) of this Article which are not correctly and completely filled and in which false and incomplete data are entered, and which certify that the residency curriculum has been delivered, that is, that the procedures and interventions completed during the residency of the residents correspond completely to the contents of the residency set out in the specialty curriculum of the healthcare workers and healthcare co-workers with a university degree;

11) the resident does not record his/her presence via the system for records of the working hours in the healthcare institution in which the module is delivered pursuant to Article 144-c paragraph (11) of this Law;

12) the resident does not meet the obligations referred to in Article 144-d paragraphs (1) and (3) of this Law for participation in a daily and morning meeting, Article 144-e paragraph (1) of this Law for mandatory trainings, Article 144-f paragraphs (1) and (3) of this Law for learning foreign languages, Article 144-h paragraph (2) of this Law for the obligations of the resident in the course of the overall duration of the specialty training, Article 144-i paragraphs (1), (2) and (5) of this Law for the obligations of the resident in the course of the first and second year of the specialty training, Article 144-m paragraphs (1), (2), (5), (7), (8), (13) and (14) of this Law for practical training in a general or special hospital, an emergency medical care service or a medical center, doing daily visiting rounds and attending autopsy, and Article 144-o paragraphs (1), (4), (5) and (6) of this Law for specialty training in surgery and internal medicine;

(7) 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 with completed higher education, that is, a healthcare co-worker with completed higher education if the misdemeanor referred to in paragraph (6) of this Article is repeated.

(8) Fine in the amount of Euro 15.000 in Denar counter value shall be imposed on the minister of health if he/she does not dismiss the director of the public healthcare institution in the cases referred to in Article 111 paragraph (1) points 12 to 14 of this Law and if he/she does not organize the publication of the data from the conducted anonymous surveys on the patients' satisfaction pursuant to Article 239-f paragraph (2) of this Law.

#### Article 313-b

(1) Fine in the amount of Euro 2.000 to 3.000 in Denar counter value shall be imposed on the person referred to in Article 106-c paragraph (1) of this Law who allows a candidate who does not meet the prescribed requirements under this Law to take the examination.

(2) Fine in the amount of Euro 10.000 in Denar counter value shall be imposed on the authorized legal entity which conducts the examination technically if it does not block the radio frequency range in the premises for holding the examination in accordance with



Article 106-d of this Law.

(3) Fine in the amount of Euro 2.000 to 3.000 in Denar counter value shall be imposed on the authorized representatives referred to in Article 106-d paragraph (4) of this Law if they allow a candidate for taking an examination for a director to act contrary to Article 106-e paragraphs (2), (3) and (4) of this Law.

(4) Fine in the amount of Euro 100 to 200 in Denar counter value shall be imposed on the candidate for taking the examination if he/she acts contrary to Article 106-e paragraphs (2), (3) and (4) of this Law.

(5) Fine in the amount of Euro 2.000 to 3.000 in Denar counter value shall be imposed on the members of the commission referred to in Article 106-k paragraph (3) of this Law if they establish irregularities in the course of the examination, but they do not note it in the report to minister of health in accordance with Article 106-k paragraph (4) of this Law.

(6) Fine in the amount of Euro 25 in Denar counter value shall be imposed for a misdemeanor on the official person in the Ministry of Health who fails to issue a decision, that is, fails to reject the request within the deadline referred to in Article 62 paragraph (1), that is, paragraph (3) of this Law.

#### 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.

#### Article 315-a

(1) With regard to the misdemeanors determined in Articles 305, 306, 307, 308, 309, 310, 311, 312, 313 and 313-a of this Law, the state sanitary and health inspector shall be obliged to issue to the perpetrator a misdemeanor payment order in accordance with the Law on Misdemeanors.

(2) The state sanitary and health inspector shall be obliged to keep records of the issued misdemeanor and on-the spot payment orders and of the outcome of the initiated procedures.

(3) The following data shall be gathered, processed and kept in the records referred to in paragraph (2) of this Article: name and surname, that is, company's name of the perpetrator, permanent, that is, temporary residence, head office, type of misdemeanor,

number of the misdemeanor, that is, on-the-spot payment order which is issued, and outcome of the procedure.

(4) The personal data referred to in paragraph (3) of this Article shall be kept for five years as of the day of entry in the records.

(5) The minister of health shall prescribe the form and the contents of the misdemeanor and on-the-spot payment order.

#### Article 315-b

The amount of the fine for the legal entity shall be determined in accordance with the Law on Misdemeanors.

## XVIII. TRANSITIONAL AND FINAL PROVISIONS

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#### 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) shall 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, 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

(1) The procedures for issuance and revocation, renewal and extension of the licenses of healthcare workers with a university degree in the field of medicine, dental medicine and pharmacy commenced under 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) 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 professional examination 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

The procedures for establishment and granting a license for work for healthcare institutions commenced under 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) and the regulations adopted thereon until the day of entry into force of this Law shall be completed in line with those regulations.

#### Article 326

The procedures for awarding the title primarius, commenced 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) and the regulations adopted thereon until the day of entry into force of this Law shall be completed in line with those regulations.

#### Article 327

(1) The professional examination for healthcare workers with a high school, two-year post secondary school and higher vocational education and for healthcare workers with a university degree shall continue to be taken 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) and the regulations adopted thereon until the formation of examination commissions in the Ministry of Health.

(2) The time spent as a trainee, 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 be considered as time spent on probationary work in accordance with this Law.

#### 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 or centers, 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 Institution – University Institute for Radiology and Public Healthcare Institution – University Institute for Biochemistry.

(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 it 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 specialties and sub-specialties training curriculum 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 specialty, that is, sub-specialty, 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 specialty, that is, sub-specialty 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 specialties and sub-specialties training curriculum, 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 specialties, that is, sub-specialties training curriculum and the resident to succeed in mastering the knowledge and skills during the specialty, that is, sub-specialty training.

(4) The co-mentor shall have the role of a guide to the resident during the specialty, that is, sub-specialty training and may guide three residents, that is, six residents in the family medicine specialty 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 of the skills under the specialty, that is, sub-specialty training curriculum, 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 specialties, that is, sub-specialties training curriculum 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

As of the day of entry into force of this Law, 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 cease to be valid.

#### 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".

### **PROVISIONS OF OTHER LAWS**

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 145/2012):

#### **Article 12**

The license granting procedures commenced 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 completed in accordance with those regulations.

#### **Article 13**

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.

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 39/2014):

**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.

The public healthcare institutions shall harmonize the statutes with the provisions of 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 27**

The procedures for taking the director examination initiated until the day of beginning of application of this Law, shall end in accordance with the provisions of the regulations under which they have been initiated.

**Article 28**

The expert commissions for cancer referred to in Article 226-b paragraphs (3) and (4) of this Law shall be formed within a period of 30 days as of the day of entry into force of this Law.

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 39/2014):

**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 has 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 December 2016.

#### **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 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 D - healthcare workers with a secondary vocational education in the field of medicine, dentistry and pharmacy, levels D4 and D5, 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 D - healthcare workers with a secondary vocational education in the field of medicine, dentistry and pharmacy, levels D4 and D5, 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.

The requirement referred to in 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 D - healthcare workers with a secondary vocational education in the field of medicine, dentistry and pharmacy, levels D4 and D5, 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 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 level of his/her position to which he/she has been assigned on the day of beginning of application of this Law, to the management body of the public healthcare institution within a period of one year as of the day of accession of the Republic of Macedonia to the European Union. 38

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 than 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.

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 43/2014):

**Article 13**

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).

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 188/2014):

**Article 2**

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", but shall start to apply as of 1 January 2015.

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 10/2015):

**Article 42** 39

The provisions of Article 16 of this Law, which amend paragraphs (2) and (3) of Article 140 paragraph (2) of this Law and six new paragraphs (4), (5), (6), (7), (8) and (9) are added, shall also apply to the residents, that is, sub-specialty trainees who, on the day of entry into force of this Law, are enrolled in specialty, that is, sub-specialty training.

**Article 43**

The provisions of Article 17 of this Law, which add a new Article 144-c and which refer to the period of professional development, the obligation of wearing a tag, and the obligation of keeping records of the presence of the resident in the course of the residency, and the provisions of Article 18 of this Law, which add a new Article 145-c and which refer to the training carried out abroad after the passing of the specialty examination, shall also apply to the residents who, at the day of entry into force of this Law, are delivering the residency in the public healthcare institutions.

**Article 45**

(1) The Government of the Republic of Macedonia shall adopt a decision on establishment of a Public Healthcare Institution University Institute for Positron Emission Tomography of the Republic of Macedonia within a period of three months as of the day of entry into force of this Law.

(2) As of the day the Public Healthcare Institution University Institute for Positron Emission Tomography of the Republic of Macedonia commences to operate, the employees from the University "Goce Delcev" in Shtip, the Faculty of Medicine, the Center for Nuclear Research

in the Field of Medicine, shall be taken over by the Public Healthcare Institution University Institute for Positron Emission Tomography of the Republic of Macedonia.

(5) The equipment, the documentation and the other means for work at the Center for Nuclear Research in the field of medicine within the University "Goce Delcev" in Shtip, the Faculty of Medicine, which are related to the carrying out of the works by the employees referred to in paragraph (2) of this Article, shall be taken over by the University Institute for Positron Emission Tomography of the Republic of Macedonia.

#### **Article 46**

The bylaws envisaged by this Law shall be adopted within a period of six months as of the day of entry into force of this Law.

#### **Article 47**

The rulebook for the specialty and sub-specialty training of healthcare workers and healthcare co-workers ("Official Gazette of the Republic of Macedonia" nos. 137/2012 and 121/2013) shall be adjusted to the provisions of this Law within a period of 3 months as of the day of entry into force of this Law.

#### **Article 48**

(1) The E-healthcare Office shall start operating as of 1 June 2015, and until the commencement of the operation of the E-healthcare Office, the Ministry of Health shall perform the works deriving from the competence of the E-healthcare Office.

(2) The director of the E-healthcare Office shall be selected no later than 1 June 2015.

(3) The acts on the internal organization and systematization of jobs in the E-healthcare Office shall be adopted within a period of three months as of the day of entry into force of this Law.

(4) As of the day the E-healthcare Office starts operating, the employees in the Ministry of Health who carry out the activities related to the integrated healthcare information system shall be taken over by the E-healthcare Office.

(5) The equipment, the documentation and the other means for work of the Ministry of Health which are related to the carrying out of the works by the employees referred to in paragraph (4) of this Article shall be taken over by the E-healthcare Office.

#### **Article 49**

(1) The minister of health shall be obliged to establish the National Commission for Preparation of the Questions and Case Studies Databases for Taking the Intermediate and Specialty Examination within a period of three months as of the day of entry into force of this Law.

(2) The National Commission for Preparation of the Questions and Case Studies Databases for Taking the Intermediate and Specialty Examination shall be obliged to prepare the questions and case studies databases for taking the intermediate and specialty examination within a period of three months as of its establishment.

#### **Article 50**

The minister of health shall be obliged to establish the National Commission for Diabetes Mellitus within a period of three months as of the day of entry into force of this Law.

**Article 51**

The minister of health shall be obliged to establish the National System for Material-Financial and Accounting Operation in the Public Healthcare Institutions within a period of six months as of the day of entry into force of this Law.

**Article 52**

The minister of health shall be obliged to establish the Central System for Electronic Records of the Working Hours within a period of six months as of the day of entry into force of this Law.

**Article 53**

The minister of health shall be obliged to establish the System for Strategic Planning and Management by Establishing a Balanced Scorecard within a period of three months as of the day of entry into force of this Law.

**Article 54**

(1) The public healthcare institutions shall be obliged to submit the request for obtaining accreditation for the first time to the Agency for Quality and Accreditation of Healthcare Institutions no later than 30 June 2016, and the Agency for Quality and Accreditation of Healthcare Institutions shall be obliged to adopt a decision establishing the fulfillment of the standards for accreditation of the healthcare institution pursuant to Article 243 paragraph (4) of the Law on Health Protection and to issue a certificate for accreditation to the healthcare institution pursuant to Article 243 paragraph (5) of the Law on Health Protection no later than 31 December 2016.

(2) The non-submission of the request for obtaining accreditation pursuant to paragraph (1) of this Article shall be regarded as non-observance of the managerial contract by the director of the public healthcare institution and grounds for imposing a contractual penalty in the amount of Euro 500.

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 10/2015 and 17/2016):

**Article 44**

(1) The provision of Article 14 of this Law, which replaces paragraph (5) of Article 121 with a new paragraph (5) and the provision of Article 17 of this Law, which adds a new Article 144-j paragraph (2) and a new Article 144-k paragraph (2) in the part that determines that ten members of the National Commission for Preparation of the Questions and Case Studies Databases for Taking the Intermediate and Specialty Examination are to meet the requirements referred to in Article 144-j paragraph (2) of this Law Article 18 of this Law, which adds a new Article 145-a paragraph (3), shall start to apply as of 1 January 2020.

(2) Until the commencement of application of the provisions of Articles 121 paragraph (5), 144-j paragraph (2) and 144-k paragraph (2) regarding the part which determines that ten members of the National Commission for Preparation of the Questions and Case Studies Databases for Taking the Intermediate and Specialty Examination are to meet the requirements referred to in Article 144-j paragraph (2) of this Law and Article 145-a paragraph (3) of this Law, the professional examination shall be taken before a commission

composed of five members who are doctors of medicine, that is, pharmacy, that is, in the field of dentistry, the National Commission for Preparation of the Questions and Case Studies Databases for Taking the Intermediate and Specialty Examination shall be composed of ten members, and the intermediate and specialty examination shall be taken before a commission composed of three members who are doctors of medicine, specialists from the same or related branch of medicine for which the specialty training is delivered, selected in academic and scientific, or scientific title, and who have published at least:

- one impact factor scientific paper until 1 January 2016,
- two impact factor scientific paper until 1 January 2017,
- three impact factor scientific paper until 1 January 2018,
- four impact factor scientific paper until 1 January 2019, and
- five impact factor scientific paper until 1 January 2020.

#### **Article 45**

(3) The provision of Article 86-a paragraph (2), added based on Article 8 of this Law, pursuant to which the Public Healthcare Institution University Institute for Positron Emission Tomography of the Republic of Macedonia may perform an activity if it employs at least five doctors in the field of medicine, that is, pharmacy and/or physics, at least two of whom are professors in a public healthcare institution in the field of medicine, pharmacy and/or physics, shall start to apply as of 01.01.2020.

(4) Until the provisions of paragraph (3) of this Law start to apply, the University Institute for Positron Emission Tomography of the Republic of Macedonia may perform an activity if it employs at least three doctors in the field of medicine, that is, pharmacy and/or physics, at least one of whom is a professor in a public healthcare institution in the field of medicine, pharmacy and/or physics.

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 154/2015):

#### **Article 10**

The bylaw determined by this Law shall be adopted within a period of 30 days as of the day of entry into force of this Law.

#### **Article 12**

The amount of the compensation for conducting the specialty, that is, sub-specialty training of healthcare workers, that is, health co-workers employed in private healthcare institutions, other legal entities and the unemployed, who do residency, that is, sub-residency on the day of entry into force of this Law shall be lower for 20% of the compensation paid by the public healthcare institutions for the healthcare workers with higher education, that is, the healthcare co-workers with higher education employed in the public healthcare institution, that is, shall be decreased for the amount of the funds the public healthcare institution where the residency is delivered receives for compensating the material costs incurred by the residency, that is, sub-residency and for improving and developing the health services in the public healthcare institution, and only compensation for the persons engaged for delivery of the practical training shall be paid to the public healthcare institution where the



residency, that is, sub-residency of healthcare workers, that is, healthcare co-workers employed in private healthcare institutions, other legal entities and unemployed persons is delivered.

### **Article 13**

(1) The healthcare workers with secondary, two-year post-secondary, and higher vocational education or 180 ECTS in the field of medicine, who have been employed in the private healthcare institutions, established based on premises and equipment lease of parts of the public healthcare institutions in accordance with the Law on Health Protection ("Official Gazette of the Republic of Macedonia" nos. 38/1991, 46/1993, 55/1995, 10/2004, 84/2005, 111/2005, 65/2006, 5/2007, 77/2008, 67/2009, 88/2010, 44/11 and 53/11) during the process of privatization of parts of public healthcare institutions where primary health protection in the field of medicine is carried out by leasing premises and equipment and based on that, establishment of private healthcare institutions, and who have lost their jobs after 1 January 2007 due to bankruptcy, that is, termination of the healthcare institution or exercise of the right to pension or death of the healthcare worker who is the holder of the activity and to whom the premises and the equipment have been leased, and who have worked in a public healthcare institution up to the day of employment in the private healthcare institutions and have not meet the requirements for exercising the right to age pension, shall be employed in another public healthcare institution in need of such healthcare workers, provided that there is no vacancy in the public healthcare institution where they have worked.

(2) The healthcare workers referred to in paragraph (1) of this Article, within a period of two years as of the day of entry into force of this Law, shall submit a request for exercising the right referred to in paragraph (1) of this Article to the Ministry of Health. They shall attach documents to the request that prove that they meet the requirements referred to in paragraph (1) of this Article, The documents shall be delivered in original or notary verified copy.

(3) The Ministry of Health, within a period of 30 days as of the receipt of the request referred to in paragraph (2) of this Article, shall decide on the request based on the submitted documentation referred to in paragraph (2) of this Article and shall issue a consent for employment of the healthcare worker referred to in paragraph (1) of this Article in another public healthcare institution in need of this type of healthcare workers, provided that there is no vacancy in the public healthcare institution where they have worked.

(4) The public healthcare institution referred to in paragraph (3) of this Article shall register the employment of the healthcare worker referred to in paragraph (1) of this Article in accordance with this Law, based on the consent of the Ministry of Health.

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 154/2015):

### **Article 14**

This Law shall enter into force on the day of its publication in the "Official Gazette of the Republic of Macedonia".

Law Amending the Law on Health Protection (“Official Gazette of the Republic of Macedonia” no. 17/2016):

**Article 45**

(1) The legal entities shops specialized for retail sale of medical devices entered in the register of shops specialized for medical devices and the legal entity – trade companies doing a business in ocular optics referred to in Article 8 of this Law which adds a new Article 96-a, should harmonize their operation with this Law within a period of three years as of the day of entry into force of this Law.

(2) The optometrists who have completed their probationary work in accordance with Article 12 of this Law which adds a new paragraph (4) in Article 117 up to the day of entry into force of this Law, should pass the professional examination within a period of one year as of the day of entry into force of this Law.

**Article 49**

The residents who have started the residency up to 31 January 2015 or have passed the specialist examination until the day of entry into force of this Law shall acquire a professional title of a specialist in the respective field of specialty without meeting the requirement referred to in Article 145-c paragraph (1) point 2) of the Law on Health Protection (“Official Gazette of the Republic of Macedonia” nos. 43/12, 145/12, 87/13, 164/13, 39/14, 43/14, 132/14, 188/14, 10/15, 61/15, 154/15 and 192/15).

**Article 50**

The price lists for the health services provided to foreigners, foreseen in Article 4 of this Law, shall be adopted within a period of 30 days as of the day of entry into force of this Law.

**Article 51**

(1) The bylaws the adoption of which is determined in this Law shall be adopted within a period of one year as of the day of entry into force of this Law.

(2) The regulations that have been in force before the day of entry into force of this Law shall apply until the adoption of the bylaws referred to in this Law.

**Article 52**

The healthcare workers holding a university degree in the field of medicine who have completed their residency and have passed the specialist examination up to the day of entry into force of this Law, shall have the right to enroll in sub-specialty training and to have their sub-residency in accordance with the curricula for sub-specialty training of healthcare workers holding a university degree in the field of medicine, as well as to take the sub-specialty examination in accordance with the regulations according to which they have completed the specialty training.

**Article 53**

The higher education institutions that are authorized to deliver specialty and sub-specialty training, shall deliver the curricula for specialty/sub-specialty training in outpatient urgent medicine and outpatient pediatrics in the duration of 36 months referred to in Article 11 of this Law to the minister of health within a period of one month as of the day of entry into force of this Law.

**Article 54**

The residents, that is, the sub-specialty trainees who have enrolled in specialty, that is, sub-specialty training up to the day of entry into force of this Law, may apply to complete the started specialty, that is, sub-specialty training as part of the co-financing program for specialty, that is, sub-specialty training under the conditions and within the deadlines set in Article 33 of this Law, which adds Articles 150-d and 150-e.

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 17/2016):

**Article 46**

Article 20 of this Law which adds a new paragraph (3) in Articles 144-j and 25 of this Law which adds a new paragraph (4) in Article 145-a shall apply until 1 January 2020.

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 37/2016):

**Article 9**

The bylaw determined by this Law shall be adopted within a period of 30 days as of the day of entry into force of this Law.

**Article 10**

The procedures initiated until the day of beginning of application of this Law shall end in accordance with the law according to which they have been initiated.

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 37/2016):

**Article 11**

The provisions of Articles 1 and 7 of this Law shall start to apply as of the beginning of application of the Law on the General Administrative Procedure in accordance with Article 141 of the Law on the General Administrative Procedure ("Official Gazette of the Republic of Macedonia" no. 124/15).

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 20/2019):

**Article 21**

The directors of the public healthcare institutions who are appointed by the day of entry into force of this Law shall be obliged to fulfill the requirement for knowledge of a foreign language within a period of one year as of the day of the appointment at the latest. The term of office of the directors who are not going to fulfill the requirement for knowledge of a foreign language within the deadline referred to in paragraph 1 of this Article shall terminate.

**Article 22 40**

The procedures for making a decision on the requests of the healthcare workers with secondary education, two-year post secondary education or higher vocational education or 180 ECTS regarding the exercise of the right to employment in the public healthcare

institution wherefrom they have been taken over, that is, in another public healthcare institution where there is a need of such type of healthcare workers, provided that there is no vacancy in the public healthcare institution wherefrom they have been taken over, initiated in accordance with the Law on Health Protection ("Official Gazette of the Republic of Macedonia" nos. 43/12, 145/12, 87/13, 164 /13, 39/14, 43/14, 132/14, 188/14, 10/15, 61/15, 154/15, 192/15, 17/16 and 37/16) by the day of entry into force of this Law, shall end in accordance with the provisions of this Law.

The healthcare workers with a university degree in the field of medicine who have obtained a license for work by the day of entry into force of this Law may specialize in accordance with the provisions of the Law on Health Protection ("Official Gazette of the Republic of Macedonia" nos. 43/12, 145/12, 87/13, 164 /13, 39/14, 43/14, 132/14, 188/14, 10/15, 61/15, 154/15, 192/15, 17/16 and 37/16).

### **Article 23**

The existing public healthcare institutions shall harmonize their operation with the provisions of this Law within a period of three months as of the day of entry into force of this Law.

### **Article 24**

The initiated procedures for approving the sending of healthcare workers with higher education in the field of medicine to specialty shall end in accordance with the Law on Healthcare Protection ("Official Gazette of the Republic of Macedonia" nos. 43/12, 145/12, 87/13, 164 /13, 39/14, 43/14, 132/14, 188/14, 10/15, 61/15, 154/15, 192/15, 17/16 and 37/16).

Law Amending the Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 101/2019):

### **Article 2**

This Law shall enter into force on the day of its publication in the "Official Gazette of the Republic of North Macedonia".

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