

NEW PUBLIC HEALTH LAW - 15 June 2009

Chapter I General provisions

Subject matter of the Law

Article 1

This Law shall regulate the essential public health functions and tasks, the system of public health, public health emergencies, and the funding of public health activities.

Purpose of the law

Article 2

The purpose of this Law shall be:

- a) to preserve and improve the health of the population;
- b) to enable implementation of the International Health Regulations 2005;
- c) to regulate specific public health issues which are not or not adequately regulated by existing legislation.

[This article will be expanded by the Ministry of Health]

Definitions

Article 3

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

1. „Public health” is the science and art of preventing disease, prolonging life and promoting health through the organised efforts of society. Public health analyses and monitors the health status of the population, and tries to improve this health status by influencing the known determinants of health (also known as risk factors) such as environmental and microbiological causes, lifestyle and socio-economic factors
2. „Essential public health functions,, are a set of fundamental activities that address the determinants of health, protect a population’s health, and treat diseases of public health significance. They prevent and manage the major contributors to the burden of disease by using effective technical, legislative, administrative, and behaviour-modifying interventions or deterrents, and thereby provide an approach for intersectoral action for health.
3. „Public health emergency” is an occurrence or imminent threat of a situation that can cause wide-spread mortality or serious morbidity from a natural disaster, infectious agent, biological toxin, or chemical or nuclear release.
4. „Public health emergency of international concern” is an extraordinary event that may constitute a public health risk to other states through the international spread of disease, and that potentially requires a co-ordinated international response

5. An “epidemic” is the occurrence in the community or region of cases of an illness, specific health-related behaviour, or other health-related events clearly in excess of normal expectancy.

6. “Prevention”: actions that prevent the occurrence of disease. Action aimed at eradicating, eliminating or minimising the impact of disease and disability.

7. “Health promotion” is the extent to which an individual or a group is able to realise aspirations and satisfy needs, and to change or cope with the environment. Health is a resource for everyday life, not the objective of living; it is a positive concept emphasising social and personal resources as well as physical capabilities.

8. “Communicable disease” is an illness due to a specific infectious agent or its toxic products that arises through transmission of that agent or its products from an infected person, animal, or reservoir to a susceptible host, either directly or indirectly through an intermediate plant or animal host, vector, or the inanimate environment.

9. A “reference laboratory” is a laboratory that carries out the control of the quality of services performed by other laboratories.

10. The “National Annual Programme of Public Health” is the standard package of services provided by Institute of Public Health of the Republic of Macedonia and all Centres of Public Health to their clients and the general population.

Principles Article 4

Public health shall be rooted in the following principles:

1. Collective responsibility for health and the leading role of the state in preservation and improvement of the health of the population;
2. Wide-ranging measures and activities focused on the entire population, and on the socio-economic determinants of health and the most significant risk factors;
3. Multidisciplinary basis and intersectoral cooperation;
4. Collection of information by means of qualitative and quantitative methods;
5. Partnership with population.

Correlation with other laws Article 5

In addition to the provisions of this law, the provisions in the laws regulating protection against communicable diseases, food safety, professional safety, environmental safety as well as other public health issues shall be applied (separate laws).

Chapter II Public health functions and tasks

Essential public health functions

Article 6

The essential public health functions are:

1. Surveillance and assessment of the population's health and well-being.
2. Identification, prediction, investigation and mitigation of health problems and health hazards in the community.
3. Health protection: technical assessment of needs and actions required to ensure health protection;
4. Disease prevention: applying interventions for primary and secondary prevention.
5. Health promotion and health education.
6. Development and enforcement of laws and regulations that protect health and ensure safety.
7. Assuring a competent multidisciplinary public health workforce.
8. Initiation, support and carrying out of health-related research.
9. Initiation, development and planning of public health policy.
10. Preparedness and management of public health emergencies, including prevention, response and mitigation of consequences.
11. Ensuring intersectoral partnership and community participation to improve health and reduce inequalities.

These Essential Public Health Functions describe the framework in which all Public Health activities are carried out by all responsible bodies, institutions and other legal entities, in which the Ministry of Health has the leading role.

Tasks of public health

Article 7

The Republic of Macedonia shall be responsible for public health by means of the following tasks:

1. Providing policy and strategy of public health;
2. Monitoring the health status of the population and identification of health problems in the community;
3. Planning, establishing priorities, passing special public health programmes, as well as passing regulations in this area;
4. Implementation of taxation, economic and other policies that stimulate healthy life styles;
5. Providing conditions for health education and empowerment of the population to take care of their own health;
6. Providing a system of quick response in extraordinary situations such as epidemics, physical and chemical accidents, and natural disasters;
7. Development of an integrated and uniform health information system;
8. Support for communities and development of intersectoral co-operation in solving health problems;
9. Evaluation of effectiveness, quality, accessibility and efficiency of health care services and programmes oriented towards the individual and the population;
10. Strengthening of laws and regulations protecting health and providing security and safety of people;

11. Provision of competence in public health human resources through training and continuing education;
12. Researching new approaches and innovation of measures in solving health problems of the population;
13. creating the conditions for a rational and standardised network of Centres for Public Health.

Chapter III

Competent authorities for implementation of the Law

Competent ministries

Article 8

The implementation of the tasks of article 7 of this Law shall be carried out by the Ministry of Health in cooperation and coordination with other ministries and institutions requiring inter-sectoral cooperation.

Institute of Public Health of the Republic of Macedonia

Article 9

The Institute of Public Health of the Republic of Macedonia (hereinafter: Institute), in addition to provisions stipulated in another law, shall perform the following:

1. Provide expert/professional assistance to the Ministry of Health in the preparation of medium-term and long-term public health plans, including the development and co-ordination - also intersectorally - of the annual general public health programme and separate interim public health programmes to be agreed by the Ministry of Health, and their budgets; these programmes are in the areas of health protection, health promotion, population screening, and monitoring and control of communicable and non-communicable diseases on the territory of the Republic of Macedonia;
2. Prepare annual national reports on relevant aspects of the population's health in agreement with the Ministry of Health;
3. Prepare standards for the scope of activities, and co-ordinate, inform and monitor the operation of the Centres for Public Health (hereinafter Centres);
4. Act as a reference laboratory for the Centres;
5. Develop and provide programmes for continuous professional development in the field of public health for its own staff, staff of the Centres, and other target groups, in co-operation with the Centres and other educational establishments in Macedonia;
6. Monitor the implementation and coordinate public health measures in case of epidemics and other emergencies on the territory of the Republic of Macedonia, together with other ministries and organisations pursuant to the Crisis Management Law;
7. Participate in international co-operation in the field of public health, shall provide health data to international organisations in accordance with law;
8. Organise and implement research in the field of public health;
9. Conduct testing of pharmaceuticals;
10. Monitor and assess ionizing radiation and non-ionizing radiation risk;

11. Assist the Ministry of Health and the other responsible ministries on issues stipulated in article 6 of this Law; and within the competencies of the Institute shall perform other tasks at the request of the Ministry of Health in the area of public health.
12. Other activities prescribed by other laws.

The activities of paragraph 1 of this Article shall be carried out through analysis, planning and assessment, health promotion, and prevention of diseases.

The subject of the scope of activities shall be in the areas of: science and research; expertise and consultancy; methodology and teaching in the field of public health; assessment of the health risks due to environmental factors, and risk factors related to the behaviour and lifestyle; research in the areas of public health, mother and child care, communicable and non-communicable diseases, including preparation for emergencies.

The Institute is to submit an annual report on its activities to the Government of the Republic of Macedonia.

Centres for Public Health Article 10

Public health tasks for the area of one (Skopje) or more municipalities shall be provided and coordinated by the Centres.

Centres are established in the area of a group of municipalities of combined number of inhabitants of at least 80,000 and the most 300,000.

Provisions of paragraph 2 of this Article shall not apply to the Centre of the city of Skopje which will cover all municipalities under the city of Skopje (urban and rural).

Article 11

The Centres, in addition to provisions in other laws and in order to address the needs of the municipalities in which they are founded shall perform the following tasks;

1. Define, prepare, and implement annual, medium-term and long-term work plans for the implementation of public health activities, including health promotion, screening of the population, and monitoring and control of communicable and non-communicable diseases for the territory under the Centre. The basis for the annual work plan of each Centre is the National Annual Programme for Public Health developed by the Institute.
2. Prepare annual evaluation reports on the health of the population, and propose measures for overcoming public health problems for the territory under the Centre.
3. Collect, process and analyze records and data stipulated in laws.
4. Monitor, analyse, and evaluate the environmental health and sanitary conditions via risk assessment, as well as propose measures for overcoming public health problems.
5. Study and monitor the hygienic and other requirements as regards to the protection of air, foodstuffs and general usage items, drinking water, surface water, waste waters and solid waste materials, and participate in the preventive sanitary supervision over construction and other works.

6. Study the nutrition of the population, as well as the diseases and conditions which emerge as a consequence from improper diet, and propose measures for the elimination thereof.
7. Microbiological and physicochemical laboratory services, analysis and evaluation of laboratory data, and propose measures for overcoming the public health problems.
8. Monitor, analyse, evaluate and implement measures for active protection of the population against occurrence of communicable and other diseases, epidemics and other emergencies, and carry out active and passive immunisation.
9. Define and implement health education for target groups.
10. Implement preventive DDD measures of public health interest.
11. Draft operational plans for its territory in the framework of the National Strategy for Protection of the Population in case of emergencies.
12. Research in the field of public health.
13. Carry out other public health activities following a request by the Ministry of Health.

Entries of paragraph 1 of this Article shall be carried out by means of analysis, planning, and evaluation; health promotion; disease control and prevention (of specific communicable and non-communicable diseases; including emergency preparedness); environmental health; and microbiology and physicochemical analysis.

In addition to items in paragraph 1 of this Article, a Centre, on the basis of an approval obtained by the Ministry of Health, can carry out certain specialised activities in the fields mentioned in paragraph 2.

Pursuant to the case in paragraph 2 of this Article, this Centre for Public Health shall serve as the leading institution for the other Centres for these specialised activities.

The Centres are to submit an annual report on their activities to the Government of the Republic of Macedonia.

National annual programme for public health Article 12

Apart from the provisions in Articles 9 and 11, the Institute and Centres are responsible for the implementation of the National Annual Programme for Public Health (hereinafter: Programme).

The Programme of paragraph 1 of this Article, following a proposal by the Ministry of Health shall be adopted by the Government of Republic of Macedonia.

The National Annual Programme for Public Health of paragraph 1 of this Article the Republic of Macedonia will contain a chapter for capital investments in the Institute and Centres based on a long term capital investment plan approved by the Ministry of Health.

In addition to the Programme of paragraph 1 of this Article, the Government of the Republic of Macedonia, following a proposal by the Ministry of Health can adopt separate special public health programmes

Article 13

Quality assurance

Quality assurance activities in the Institute and Centres will consist of developing and following agreed professional standards and guidelines, continuing professional development of staff, accreditation of laboratories, and peer review.

The Institute and the Centres are themselves responsible for assuring the quality of the services they provide according to jointly developed guidelines. In their annual reports they will describe their efforts and results in this field in the past year and their commitments for the coming year. The Institute will oversee the activities of the Centres according to a jointly developed protocol.

The Institute will provide reference laboratory services for the laboratories of the Centres according to a jointly agreed schedule.

The Institute and the Centres will provide sufficient opportunities for continuing professional development to their technical and academic staff to maintain the required level of expertise. The Institute will assist the educational activities of the Centres as required.

The laboratories of the Institute and the Centres must be accredited according to the Law on Accreditation.

Article 14

In response to the public health needs and emergencies, the Institute and Centres shall provide technical and expert assistance to the inspectors of the State Sanitary and Health Inspectorate and the Food Directorate, shall submit data and information to the State Sanitary and Health Inspectorate and Food Directorate, necessary for ordering measures by the State Sanitary and Health Inspectorate and Food Directorate to natural persons and legal entities, pursuant to this or another law.

For the delivery of certain measures stipulated in this or another law, teams comprised of representatives from the Institute and Centres and the Inspectorate and Food Directorate can be formed.

Coordination and cooperation

Chapter IV

System of public health

Article 15

The system of public health that provides conditions for preservation and improvement of the population's health is comprised of citizens, families, employers and employees, educational and other institutions, humanitarian, religious, sport and other organisations, associations, public health and health care institutions, health insurance funds, as well as municipalities and the Government of the Republic of Macedonia, and other state and non-state organisations and institutions.

The partners in paragraph 1 of this Article are responsible for participating in the implementation of the essential public health functions from Article 6 of this law.

The provision and implementation of the public health functions in the country shall be the right and responsibility of Republic of Macedonia, the Ministry of Health, the Institute, the Centres, the State Sanitary and Health Inspectorate, the Food Directorate, ministries in charge of education, environmental protection, social care/

protection, science, sports, culture, traffic, agriculture, economy, labour and other authorities and bodies as stipulated in this and other laws.

The Institute and the Centres have the leading role in the system of public health, as well as in the implementation of the essential public health functions of article 6 of this Law.

Competencies and tasks of other participants in the system of public health are determined by other laws and regulations.

In the course of implementing the public health functions of Article 6 of this Law, the following shall participate: citizens, families, employers and employees, educational and other institutions, humanitarian, religious, sport and other organisations, associations, public health and health care institutions, health insurance funds, as well as municipalities and the Government of the Republic of Macedonia, and other institutions as well as non-governmental organizations.

In addition to the Ministry of Health, other ministries engaged in areas of education, environmental protection, social care/ protection, science, sports, culture, traffic, agriculture, economy, labour shall secure delivery of the public health functions pursuant to this and other laws.

Article 16

The Institute and the Centres shall position the delivery of operations stipulated in Article 9 and Article 11 of this Law in the following principles:

1. Clearly defined public health purpose.
2. Public health procedures based on modern, scientifically sound principles and evidence.
3. Well-targeted public health interventions by involving the optimal number of persons in accordance with public health standards.
4. Undertaking public health intervention which is least restrictive to the rights and interests of individuals in the course of protecting public health;
5. Undertaking public health intervention which will not in an unlawful manner discriminate individuals on the basis of their race, ethnicity, nationality, religious beliefs, sex, sexual orientation, or disability status.
6. Respect the dignity of each individual during a public health intervention

National Council for Coordination of Public Health

Article 17

The Government of Republic of Macedonia shall establish a National Council for Public Health (hereinafter: National Council) as an advisory body dealing with public health issues of shared competency scope of two or more ministries.

The National Council shall study the public health issues and policies, shall prepare opinions, initiatives and/or proposals to submit to the competent authorities for the implementation of this law.

The National Council shall be comprised of _____ representatives from the Ministry of Health, Ministry of Environment and Physical Planning, Ministry of Labour and Social Policy, Ministry of Education and Science, Ministry of Agriculture, the Ministry of Local Self-Government, the Institute and independent experts in the area

of public health in the course of which one should consider an equal representation of the entire population in Republic of Macedonia.

The National Council shall be chaired by the Minister of Health.

The mandate of the members of the National Council shall be 5 years.

The National Council, the coordinative body of paragraph 1 of this Article shall adopt Rules of Procedure.

Councils for Public Health **Article 18**

The Government of the Republic of Macedonia shall form Councils for Public Health (hereinafter: Council) which shall advise the Centres and the municipalities on the territory of each Centre, upon their request and also at their own initiative, on all public health matters that involve other partners than the Centre.

The Council of paragraph 1 of this Article shall comprise of at least 7 members, of which at least 3 shall represent the municipalities on whose territory the Centre is established, and other 2 independent public health experts.

The membership of the Council shall elect the chairperson.

The mandate of the members of the Council shall be 5 years.

The Council shall adopt rules of procedure for its operation.

For the territory of Skopje, a Skopje Public Health Council shall be established. As regards to the composition and the operation of the Council of paragraph 5 of this Article, paragraphs 1 to 5 shall be respectively applied.

The role of the units of self-government in the delivery of public health **Article 19**

The units of the local self government can deliver public health activities for their own territory for which purpose they have self-generated funds.

The units of the local self government within the inter-municipal cooperation can found a joint working body, committee, coordinative or other expert authority for the purpose of exchange of information, experiences and coordination of the public health cooperation for the territory of their municipality, in accordance with law.

Public health emergencies **Chapter V**

Public health emergencies causes by infectious disease epidemics **Article 20**

In case of an epidemic of communicable disease on the territory of one or more Centres, the Centre(s) will inform the Ministry of Health and the Institute.

If there is a risk of the epidemic spreading beyond the borders of the Republic of Macedonia, the National Focal Point will inform the Contact Point of the World Health Organisation..

The Ministry of Health will decide if the epidemic is a public health emergency that

warrants the involvement of the Crisis Management Centre.

If the epidemic does not represent a public health emergency, the epidemic control measures will be undertaken by the Ministry of Health and agencies thereof.

Public health occurrence of international concern

Article 21

In cases of suspected public health occurrence of international concern prescribed by the International Health Regulations, the Centre/Centres shall inform the Ministry of Health and the Institute.

The Ministry of Health shall decide if the public health occurrence is of international concern, in accordance with the decision-making assessment instruments stipulated in the International Health Regulations.

In cases of public health occurrence of international concern prescribed in the International Health Regulations, the National Focal Point shall inform the Contact Centre in the World Organization according to notification instrument appropriate for such instances, set forth in the International Health Regulations.

Public health emergencies of a non- infectious nature

Article 22

In case of a public health emergency of a non-infectious nature, the Crisis Management Centre will be in charge of control of the emergency according to the Crisis Law, in co-operation with the Ministry of Health, the Institute, and the Centres.

If the public health emergency of paragraph 1 of this Article is of international concern pursuant to the International Health Regulations, the Institute shall inform the Contact Centre of the World Health Organization within 24 hours following the assessment of the public health information.

Application of the International Health Regulation

Chapter VI

National Focal Point

Article 23

The Institute shall be the National Focal Point for the application of the health measures from the International Health Regulations.

Acting in instances of suspicion of a presence of an onboard infectious disease

Article 24

The captain of an aeroplane in an international flight who wants to land at the airport, and who knows or seriously suspects that one or more passengers on board of the aircraft show signs of an infectious disease that may endanger public health, must inform the air traffic controller or the operator at the airport immediately after discovering and before landing.

The air traffic controller must immediately inform the operator of the airport whereas the later shall inform the responsible person of the medical team of the airport
The responsible person of the medical team of the airport shall immediately inform the State Sanitary and Health Inspectorate and the Institute of Public Health of Republic of Macedonia.

General declaration of the aircraft and other information

Article 25

Pursuant to a request by the State Sanitary and Health Inspectorate, the captain of the airplane in charge of the international flight shall prepare and submit the Health Part of the Aircraft General Declaration prepared in accordance with the International Health Regulations.

In addition to the Health Part of paragraph 1 of this Article the State Sanitary and Health Inspectorate can ask the captain for additional information about the airplane regarding the health situation of the passengers on board.

Entry point

Article 26

The Minister for Transport following an opinion stated by the Minister of Health shall designate the airport(s) which is/are to be the entry point(s) to which the International Health Regulations apply.

The airport(s) of paragraph 1 of this Article is/are obliged to develop its/their capacities as prescribed by the International Health Regulation.

In case of accepting notification of Article 24, or if suspicion of a potential public health danger on board of an aeroplane has arisen otherwise, the Minister of Transport, after consultation with the Minister of Health, can determine at which airport the aeroplane should land.

State Sanitary and Health Inspectorate actions

Article 27

In case of article 24 of this law, the State Sanitary and Health Inspectorate shall order a list of measures to be applied upon arrival of the airplane in the airport.

In case of a direct threat of an epidemic of an infectious disease, the State Sanitary and Health Inspectorate will decide on measures which must be taken regarding the admission of crew and passengers of the aeroplane.

In cases of paragraphs 1 and 2 of this Article, the captain of the aeroplane will assure that after landing of aircraft, nobody is to enter or exit the aircraft, and no goods will be loaded or unloaded, until permission of the State Sanitary and Health Inspectorate is obtained.

The captain of the aircraft shall, upon request, submit a list with the names, address, sex, age and destination of the passengers to the State Sanitary and Health Inspectorate.

Article 28

The State Sanitary and Health Inspectorate can order the operator of the airport:

- a) to give information to passengers to take measures to prevent infection or contamination of the luggage;
- b) to assist the Institute or the State Sanitary and Health Inspectorate with the investigation of departing or arriving passengers for the presence of an infectious disease with a risk of serious danger to the public health;
- c) to carry out technical-hygienic measures for the prevention of contamination, if there is a well-founded risk of contamination;
- d) to close buildings or sites, or parts thereof, for the control of contamination.

Article 29

The State Sanitary and Health Inspectorate can order the operator of an aircraft:

- a) to give information to passengers to take measures to prevent infection or contamination of the luggage;
- b) to carry out technical-hygienic measures on the aircraft and its cargo for the prevention of contamination, if there is a well-founded risk of contamination;
- c) to check an aircraft and its cargo for the presence of contamination;
- d) to disinfect an aircraft and its cargo for the control of contamination, including the destruction of vectors.

Road border crossings

Article 30

Aspects of the International Health Regulations that pertain to designated ground border crossings shall be regulated by the Law on the Protection of the Population from Communicable Diseases.

Active and passive immunisation and prophylaxis

Article 31

Active or passive immunisation of persons or the use of prophylaxis in order to obtain an internationally valid certificate as described in the International Health Regulations will be provided according to the provisions of the Law on the Protection of the Population from Communicable Diseases.

Shape and content of the certificates of paragraph 1 of this Article are prescribed by the International Health Regulations.

The Minister of Health will designate institutions that can provide immunisation against yellow fever and other types of immunisation only used for specific target groups.

Airport Operators Costs

Article 32

The operators of airports as well as operators of aircrafts shall cover all costs for the implementation of the measures of this law and the International Health Regulations.

Article 33

The Minister for Health shall publish the International Health Regulations.

Special provisions
Chapter VII

Article 34

[Establishment of a coordinating body for food safety matters; text will be provided by the Food Directorate.]

Article 35

[Responsibility for food risk management; text will be provided by the Food Directorate.]

Article 36

An entrepreneur who is not a medical doctor and who performs activities that penetrate the skin of his clients needs a permit from the Ministry of Health. Activities of paragraph 1 of this Article include tattooing, piercing, permanent make-up and acupuncture.

Article 37

A natural person or legal entity can perform skin work such as tattooing, piercing, permanent make-up and acupuncture if adequate facilities, equipment, skilled staff and appropriate materials are secured.

Tattooing or piercing except in the earlobe is prohibited for persons under the age of 16.

For persons above the age of 16 and under the age of 18 a written parental or guardian's approval is required for tattoos on head, neck, wrists or hands, and for genital piercing (boys and girls) and nipple piercing (girls only).

For persons receiving a piercing or a tattoo a prior elaboration of possible consequences is compulsory.

Tattooing, piercing, permanent make-up and acupuncture can be performed only in premises prescribed by the Minister of Health.

Modalities regarding the facilities, equipment and skilled staff shall be prescribed by the Minister of Health.

Article 38

The Minister of Health shall assess if the requirements of Article 37 of this Law have been met, and shall adopt a decision for authorizing/ permitting work.

The work permit of paragraph 1 of this Article can be revoked if changes occur as a cause of which significant deviation according to Article 37 of this law have been performed.

Provision of information on the health effects of cosmetic services

Article 39

The Ministry of Health may, by secondary legislation, require non-medical providers of cosmetic services that do not penetrate the skin of clients but may pose a health risk to the clients, to provide information to the clients regarding the health effects of their services.

The secondary legislation of paragraph 1 of this Article may, in particular:

- a. specify the information which is to be provided;
- b. require the information to be provided in a particular form;
- c. specify the manner in which that information is to be provided or displayed.

Financing of public health activities Chapter VIII

Sources of financing Article 40

Funds for public health funding shall be secured from the following sources:

- Budget of the Republic of Macedonia;
- self-generated income;
- Health Insurance Fund of the Republic of Macedonia under conditions stipulated in this law;
- donations and
- other sources of revenue regulated in another law.

Funds from the Budget of Republic of Macedonia Article 41

Resources for funding the public health scope of activities shall be secured by the Budget of Republic of Macedonia in a manner stipulated according to the Law on Budgets of Republic of Macedonia and the Law on Execution of Budget of the Republic of Macedonia.

Allocation of resources from the Budget of Republic of Macedonia Article 42

The funding of operations of the Institute and Centres shall be carried out according to a financial plan and programmes, and an annual calculation adopted by the Ministry of Health.

The Institute and Centres will be financed for their activities under the National Annual Programme for Public Health of Article 12 of this law according to a resource allocation formula established by the Minister of Health. Per capita funding according to the number of inhabitants in their territory will be an important element of this formula.

The financial plans of paragraph 1 and 2 of this Article will contain a chapter for capital investments based on a long-term capital investment plan approved by the Ministry of Health.

Control over the earmarked utilization of the resources from the Budget of the Republic of Macedonia Article 43

The Ministry shall control the earmarked utilization of the funds allocated from the Budget of the Republic of Macedonia.

Mandatory insurance
Article 44

The Institute and the Centres shall sign up for an adequate damage liability insurance for which the founder- the Budget of the Republic of Macedonia shall secure funds.

Self- generated income
Article 45

The Institute can generate income by providing services to natural persons and legal entities, provided such services can not be provided by the Centres.
The pricing of paragraph 1 of this article shall be defined according to a tariff book.
The tariff book of paragraph 2 of this article shall be adopted by the Minister of Health.

Funds from the Health Insurance Fund

Article 46

In cases when the Centres provide diagnostic-laboratory services to individually insured patients according to a referral, the expenses for such services are to be covered by the Health Insurance Fund of the Republic of Macedonia.

Donation revenues
Article 47

Financial or material items can constitute a donation.
Donors could be domestic and international natural or legal entities.
The purpose and modality of use of donations are to be regulated with a contract between the donor and the Institute, or the Centre.

Supervision
Chapter IX
Article 48

Supervision over the application of this Law shall be carried out by the Ministry of Health.
Inspection supervision over the implementation of the provisions of this Law shall be carried out by the State Sanitary and Health Inspectorate compliant to the Law on Sanitary and Health Inspectorate.

Penal provisions
Chapter X
Article 49

Fine in the amount of ____ to ____ EUR in MKD equivalent value shall be issued for a misdemeanour to an entrepreneur carrying out activities of Article 36 of this law without a permit.

Final provisions
Chapter XI

Institute for mother and child care
Article 50

On the day of entering into force of this Law, the Institute for Mother and Child Care as such shall cease to exist.

All employees, movable and immovable property and other assets of the Institute for Mother and Child Care are to be taken on by the Institute.

Article 51

On the day of entering into force of this Law, Article 117 of the Health Care Law shall cease to apply except for its first paragraph.

Enactment
Article 52

This Law shall enter into force on the eight day following the publication in the “Official Gazette of Republic of Macedonia”