



Republika e Kosovës
Republika Kosovo - Republic of Kosovo
Kuvendi - Skupština - Assembly

Law No. 04/L-125

ON HEALTH

Assembly of Republic of Kosovo,

Based on Article 65 (1) of the Constitution of the Republic of Kosovo;

Approves:

LAW ON HEALTH

CHAPTER I
BASIC PROVISIONS

Article 1
Purpose of the law

This law has the aim of establishing legal grounds for the protection and the improvement of the health of the citizens of the Republic of Kosovo through health promotion, preventive activities and provision of comprehensive and quality healthcare services.

Article 2
Scope

1. This Law defines:

- 1.1. rights and obligations in the field of health;
- 1.2. the healthcare principles;
- 1.3. the healthcare system;

- 1.4.healthcare institutions' activities;
- 1.5.supervision of healthcare services.

Article 3 **Definitions**

1. Terms used in this Law shall have the following meaning:

- 1.1.**The Government** - the Government of the Republic of Kosovo;
- 1.2.**The Ministry** - the Ministry of Health;
- 1.3. **Municipality** - the basic territorial unit of local self-governance in the Republic of Kosovo;
- 1.4.**The citizen** - person with citizenship of the Republic of Kosovo according to the Law on Citizenship of Kosovo, or person qualified as a refugee in compliance with the law;
- 1.5. **Resident** - a bearer of a stay permit issued by the competent authority, for the territory of the Republic of Kosovo as well as the person with official refugee status;
- 1.6. **User of healthcare services** - a person using the healthcare services;
- 1.7. **Close family member**, the spouse; the child adopted child; parent (step-father, step-mother); brother and sister, up to the age of eighteen (18);
- 1.8. **Person with special needs** - a person with temporary or permanent and full disability older than eighteen (18) and under sixty five (65), who has the medical diagnosis of a such physical, sensory and mental state; of the illness or disability, which makes him unable to have any profitable job and for which, after the professional assessment the relevant Ministry has taken the decision that it fulfills the criteria set by the law;
- 1.9. **Work disabled person** - a person who based on the law is recognized the right on work disability;
- 1.10. **War disabled person** - a member of the Kosovo Liberation Army, who based on the law is recognized the right on disability due to the war;
- 1.11. **Civilian war disabled person** - is the person who is recognized the right on disability as a consequence of war and political imprisonment;
- 1.12.**Health Financing Agency (HFA)** - executive Agency of the Ministry, successor of public health insurance fund , that on behalf of the state realizes the rights, obligations, responsibilities, and authorizations regarding contracting, buying healthcare services from healthcare institutions in all forms of ownership, as well as pooling all financial means for this purpose.

1.13. **Health Insurance Fund** –public health insurance institution as a legal person that has the rights, obligations, responsibilities and authorities defined by a separate Law.

1.14. **Accreditation**- the procedure of official recognition, by an authorized body from the Ministry, of a competence of a health institution for assessment of conformity with standards and technical rules in order to perform a health activity for which it has been licenced.

1.15. **Licensing** – the procedure for granting the licence to the professional or health institution that deals with health activities in Kosovo and is authorized to practice health activity in accordance with the applicable law in Kosovo.

1.16. **List of drugs and medical consumables** - the List of medical products and medical consumables covered by the Government and by co-payments;

1.17. **Copayment** - financial means that with the purpose of financing the healthcare services are paid by citizens and residents whom by this law are not exempted from copayments for use of healthcare services in public or private institutions, or that is a part of public-private healthcare partnership, contracted by the HFA;

1.18. **Hospital and University Clinical Service of Kosovo** - an independent health organization with a special public importance at the level of secondary and tertiary healthcare, as a legal person, that has the rights, obligations, responsibilities and powers as defined in this Law.

1.19. **List of healthcare services** - list of forms and types of health care services that shall be covered by the Government and by copayments (including the list of drugs and medical consumables), developed based on agreed criteria by a technical committee appointed by the Minister of Health. The List can be modified as needed upon the assessment of the Ministry.

1.20. **Health professional** - a worker providing healthcare services;

1.21. **Graduated** - a person who has completed his university studies;

1.22. **Specialist** - professional qualification gained during post-graduate specialist education carried out in the Republic of Kosovo or abroad, recognized and verified in compliance with this law;

1.23. **Sub-specialist** - narrow professional qualification gained during post-specialist training in the Republic of Kosovo or abroad, recognized and verified by the authorized or recognized authority in compliance with this law;

1.24. **Health co-worker** - a person working in healthcare institutions who has not completed the formal medical education, but who is employed in a healthcare institution with the aim of realizing health activities;

1.25. **Healthcare services in prisons in the Republic of Kosovo** - a professional autonomous health service, taking care continuously and comprehensively for the health of the citizens and residents placed in correctional institutions;

1.26. **Healthcare** - the measures and activities undertaken by organizations, institutions and health professionals with the primary purpose to improve the health of the citizens and residents;

1.27. **Family medicine** - personal, comprehensive and continuing care for the individual in the context of the family and the community;

1.28. **Professional service** - the administrative and professional organization of healthcare institutions within one specialist field aiming to provide continuous healthcare at all levels of the healthcare services organization;

1.29. **Healthcare institution** - institution established by juridical or physical persons providing healthcare services under a working license issued in compliance with this law;

1.30. **Humanitarian healthcare institution** - a healthcare institution established by non-governmental and non-profitable organizations in the Republic of Kosovo licenced to provide healthcare services;

1.31. **Founder** - Ministry, Municipal Assembly and natural persons and legal entities having the right to establish a healthcare institution in compliance with this Law;

1.32. **The health documentation** - the manuscripts, records and the data collected, regarding the personal identity of the healthcare user and his health status accessible to the health professional during the provision of healthcare services;

1.33. **Professional confidentiality** - keeping confidential the data about the health status of the healthcare user from unauthorized access;

1.34. **Emergency** - immediate change occurring in the health status, which in a situation of lack of an urgent healthcare, poses a risk of death or of serious damage to the health of the citizen and resident;

1.35. **Urgency** - immediate change occurring in the health status, that requires a urgent health case, but does not pose a direct risk of death or of serious damage to the health of the citizen and resident;

1.36. **State of urgency**- any unexpected situation that endangers the life, integrity and health of the citizens and residents or disrupts functioning of the healthcare institutions to the level that brings to the serious disproportion between the needs for the healthcare and resources available;

1.37. **Artificial sterilization** - medical procedure having as an aim the loss of ability for childbirth;

1.38. **Transplant** - the organs, tissues, and cells of human or animal origin destined to be transferred in a human;

1.39. **Transplantation** - removal of the transplant within the same body; from one body to another within same or different species; and from one to another genetically identical bodies, only for medical needs and when is considered necessary to save the life and health of the receiver of the transplant;

1.40. **Assisted fertilization** - a process through which the ovary is fertilized with a spermatozoid outside the body, *in vitro*;

1.41. **Para-medical and alternative treatment** - the treatment methods verified by professional health associations which are not in compliance with the current medical doctrine and due to that are not part of the official healthcare services.

2. In this law, except for the cases when the context implies differently: singular includes plural and plural includes singular; and “he” includes “she” and “his” includes “her”.

Article 4 Rights and responsibilities in healthcare

1. Implementation of this law shall be in full compliance with the human dignity, fundamental rights and freedoms set by the Constitution of the Republic of Kosovo, international covenants and legislation guaranteed by the Constitution and directly implemented in the Republic of Kosovo.

2. All the citizens and residents have the right to equal access in healthcare.

3. Every citizen and resident is obliged to take care of his health.

4. The citizens and residents, take active part in creating favorable conditions for implementation of healthcare activities and realizing their rights within this activity, in an organized manner, through associations or appointed individuals.

5. The rights and responsibilities of the citizens, residents, and other healthcare users are regulated by the Law on rights and responsibilities of citizens in healthcare.

CHAPTER II HEALTHCARE

Article 5 The principles of implementation in healthcare

1. The provision of healthcare is based on the following principles:

1.1. Equity

1.1.1. assuring all citizens' and residents full access to services in the List of healthcare services after it has been defined; including easy access to the healthcare facilities for the persons with disability;

1.1.2. equitable distribution of public resources for health, taking into account socioeconomic difference;

1.1.3. equity between the public sector, private sector, and public-private partnership in compliance with this law.

1.2. inclusiveness and non-discrimination: equal healthcare for all citizens and residents by ensuring the standards during fulfilling the needs at all levels of healthcare as well as ensuring healthcare without discrimination on basis of: gender, nation, race, color, language, religion, political preferences, social status, sexual orientation, the level of physical or mental abilities, family status, or age;

1.3. quality: Applying international standards in organization, development and provision of healthcare with respect to all aspects including: patient focused treatment, resources use, organization of: work, training, education, licensing, accreditation, ethical guidelines, and protection of interests of users of healthcare services.

1.4. honesty and accountability;

1.5. prioritization of evidence-based, cost-effective interventions in health care;

1.6. sustainability and continuity;

1.7. prevention and early detection of illnesses through health promotion and multi-sectoral public policies and screening to improve health.

1.8. co-responsibility and solidarity,

Article 6 **Healthcare activity**

Institutions of the Republic of Kosovo; healthcare institutions; legal and natural persons, within their rights and obligations shall take necessary measures to ensure and implement the healthcare principles and healthcare measures, according to policies and priorities established by the Ministry.

Article 7 **Supervision of healthcare activity**

1. Healthcare activity is an activity of special public interest.

2. Healthcare services and activities are subject to legal supervision ensured by the Ministry and professional supervision ensured by the Chambers of Health Professionals from article 78 of this law.

CHAPTER III DEVELOPMENT POLICIES IN HEALTH

Article 8 Healthcare policies

1. The Ministry develops policies and implements laws of a non-discriminatory and responsible healthcare system based on professional analysis and the scientific data.
2. The Ministry shall establish normatives and standards and develop regulations for the health sector, respecting relevant international standards;
3. The Ministry undertakes all measures defined by law for the implementation of necessary actions to ensure and protect the rights of citizens, residents, and other healthcare users, in healthcare.

Article 9 Stewardship and Regulatory Functions

1. Stewardship and regulatory functions of the Ministry include:
 - 1.1. developing and guiding implementation of policies and legislation for a non-discriminatory and accountable healthcare system;
 - 1.2. coordinate activities to promote coherent development and implementation of healthcare policies;
 - 1.3. set up norms and standards and issue administrative instructions for the health sector with due regard to relevant international standards;
 - 1.4. supervise implementation of standards from subparagraph 1.3. paragraph 1. of this Article, including inspections and other services, as needed;
 - 1.5. monitor the situation and implement appropriate measures to prevent, identify and solve problems in the health sector;
 - 1.6. manage and develop the infrastructure related to healthcare;
 - 1.7. development of the institutional and human resources in the health sector necessary to reduce treatment out of the country;
 - 1.8. promote participation, initiatives and the development of citizens' and residents activities related to health;
 - 1.9. development and participation in the campaigns on public information and other healthcare promotion projects to increase public awareness and compliance with health standards;

1.10. encouraging development of health education in order to raise knowledge and competencies in the health field;

1.11. supervision of the water and food quality control services in order to protect consumers, in coordination with the competent ministries, in compliance with the law.

1.12. planning of human resources in the health sector;

1.13. the Ministry, where appropriate, shall establish commissions, committees, boards and professional counsels for certain fields and issues, in compliance with the law. and relevant sub-legal acts.

Article 10

Health Care Development Policies

1. Implementation of the healthcare development policies is responsibility of the Ministry which via sectoral plans, organization, financing, standards, regulation and management shall provide incentive for the improvement of the health by guiding the behavior of other government institutions, municipalities, employees, employers, civic society, citizens, residents, and the health care system.

2. The healthcare development policy shall be defined through:

2.1. strategic plans;

2.2. mid-term plans;

2.3. operational plans.

3. Strategic, mid-term, and operational plans shall be elaborated based on the criteria and the planning cycles established by the Government.

4. The strategic plan is approved by the Assembly of Kosovo.

5. The mid-term healthcare development plan is approved by the Government.

6. The Ministry on the proposal of the Municipal Assembly approves the operational plan for the development of primary healthcare, in compliance with the mid-term plan approved by the Government.

7. The Government approves the operational plan for development of the secondary and tertiary healthcare.

8. The detailed procedures regarding preparation of strategic, mid-term and operational plans for all healthcare levels shall be determined by a sub-legal act issued by the Ministry.

CHAPTER IV HEALTHCARE IMPLEMENTATION

Article 11 Services

1. Healthcare services are provided and organized by healthcare providers as: inpatient, outpatient, home, and emergency services.
2. Healthcare services are provided in compliance with the procedures and conditions set by this Law and relevant sub-legal acts.
3. Healthcare services for persons who are not citizens or residents of the Republic of Kosovo shall be done with payments and shall be regulated by a sub-legal act, issued by the Ministry.

Article 12 Measures and activities

1. Healthcare shall be implemented through the following measures and actions:
 - 1.1. preservation and promotion of the healthy lifestyles through health promotion and educative activities organized with the aim of raising citizens' and residents health culture;
 - 1.2. early detection of the communicable diseases and elimination of their causes by changing conditions, which cause the epidemics;
 - 1.3. early detection of the acute diseases, and treatment of the chronic mass non-contagious diseases, from the official register, included related rehabilitation;
 - 1.4. prevention and early detection of malignant diseases, particularly breast cancer, cancer of the neck of uterus, and colorectal cancer;
 - 1.5. prevention and early treatment of injuries in work place and occupational diseases;
 - 1.6. prevention and early detention and treatment of drug addictions, sexually transmitted diseases and HIV infection;
 - 1.7. provision with: drugs, medical supplies, and equipment;
 - 1.8. treatment, rehabilitation and re-socialization of the chronically mentally ill patients in the community;
 - 1.9. treatment, psychosocial rehabilitation and re-socialization of the persons with special needs in the community;

- 1.10. provision of the necessary conditions for the pregnant women and women after childbirth, and healthy development of children and youth;
- 1.11. measures for prevention and elimination of health consequences caused by emergency conditions;
- 1.12. organization of the emergency healthcare services based on the separate law;
- 1.13. implementation of the uniform system for data collection and health information;
- 1.14. organization and implementation of the professional and legal supervision;
- 1.15. implementation of the activities related to voluntary blood collection;
- 1.16. taking measures related to the protection against environmental harmful causes; physical, chemical and biological;
- 1.17. prevention and early detection of congenital abnormalities;
- 1.18. prevention and early detection of caries, oral diseases and oro-facial abnormalities;
- 1.19. healthcare services of patronage at home for citizens and residents in need, especially for paralyzed persons;

Article 13 Standards

1. The best healthcare practices shall be set in the form of clinical practice guidelines, standards, protocols and other recommendations by the chambers of health professionals from Article 78 of this law, in cooperation with respective professional associations.
2. In implementing healthcare, healthcare institutions, health professionals, legal persons citizens, and residents, within their rights and responsibilities should take the required measures to ensure quality and quantity standards of healthcare, set by a sub-legal act issued by the Ministry.
3. The system of quality healthcare management shall be determined by sub legal act from paragraph 2. of this Article.

Article 14 Healthcare implementation conditions and procedures

1. Healthcare is implemented in healthcare institutions or at the citizen's or resident's home or other places when the citizen or resident needs urgent healthcare.

2. Healthcare is provided in healthcare institutions according to the conditions and procedures set by the law, sub-legal acts, as well as other internal acts of the healthcare institution.
3. Healthcare in other forms of health activity is provided according to the conditions and procedures set by the law and sub-legal acts.
4. Healthcare activity of foreign citizens is regulated by a sub-legal act, proposed by the Ministry, and approved by the Government.

CHAPTER V ORGANIZATION OF HEALTHCARE

Article 15 Healthcare levels

1. Healthcare is organized and shall be implemented at three (3) levels: primary, secondary and tertiary.
2. Healthcare services are provided by public, private and public-private healthcare institutions.
3. Healthcare services are provided at state, municipal, employer level and individually in a professional service level.
4. Distribution of activities among healthcare levels shall be conducted in compliance with the national health strategy, as well as based on the principle of primary healthcare as an entrance point and foundation of the health system.
5. Access to healthcare shall be provided on twenty four (24)-hour basis, continually, through the regular work, shift-work, on-duty work and emergency services work, in compliance with the working time set by the healthcare institution.

Article 16 Unique System

1. The Ministry regulates, supervises, and controls the provision of healthcare in public, private healthcare institutions, at all three levels of healthcare.
2. The healthcare at the three levels of organization is ensured within the unique system only by licensed healthcare institutions in accordance with this law and the relevant sub-legal acts.
3. The continuity and comprehensiveness of the healthcare services at the three (3) levels of care is ensured through the strict implementation of the referral system from the primary level to the secondary level, and from the secondary to the tertiary level healthcare as well as implementation of mutual coordination and communication between the levels of healthcare.

Article 17
The types of healthcare institutions

1. The institutional structure of the health system in the Republic of Kosovo is the same for public, private, or public-private sector.

2. The Primary healthcare institutions are:

2.1. Main Family Health Centre with its constitutive units determined by a sub-legal act issued by the Ministry;

3. The Secondary healthcare institutions are:

3.1. general and special hospital with its constitutive units determined in the sub-legal act issued by the Ministry;

3.2. specialist polyclinic;

3.3. specialist ambulance;

3.4. dentist ambulance;

3.5. mental health centre with Home for integration in the community;

3.6. blood transfusion centre;

3.7. physical and climatic rehabilitation centre;

3.8. sports medicine centre;

3.9. occupational medicine centre;

3.10. regional public health centre.

3.11. hearing and speaking rehabilitation centre.

4. The Tertiary healthcare institutions are:

4.1. university clinical centre;

4.2. university dentistry clinical centre;

4.3. national institute of public health;

4.4. national occupational medicine centre;

4.5. national sports medicine centre;

4.6. national blood transfusion centre;

- 4.7. national centre of telemedicine;
5. Pharmacies are healthcare institutions that function at all three (3) levels of the healthcare.
6. Institutions in prison healthcare services are:
 - 6.1. prison ambulant;
 - 6.2. prison stationary;
 - 6.3. healthcare institution for treatment of persons with special needs;
 - 6.4. healthcare institutions for mother and child care.

Article 18 **Primary healthcare**

1. Primary healthcare shall be provided in compliance with the policies, plans and standards set by the sub-legal act issued by the Ministry.
2. Primary healthcare includes:
 - 2.1. health promotion, prevention, early detection and diagnosing, treatment, and rehabilitation related to diseases, disorders and injuries, including small surgical interventions;
 - 2.2. preventive protection through the promotion of health programs and systematic visits of children and youth in primary, secondary and high schools in the territory of the municipality;
 - 2.3. protection and advancement of public health, including sero-prophylaxy, vaxio-prophylaxy, and chemo-prophylaxy in compliance with law, as well as systematic health education of the population;
 - 2.4. promotion of oral health and dental healthcare;
 - 2.5. early diagnosing and treatment of tuberculosis;
 - 2.6. organization of urgency and emergency medical services as part of the unique system of emergency medical services.;
 - 2.7. child and mother health care services and family planning.
 - 2.8. mental health services.
3. Municipalities are responsible for public primary healthcare and for assessment of the health status of population in their territory.

4. The municipalities are obliged to implement, priority health promotion and health preventive measures of healthcare.
5. Primary healthcare services are provided and implemented within a framework of family medicine services, in a compliance with sub-legal act issued by the Ministry.
6. Constitution of a Family Medicine Team is set by the sub-legal act from paragraph 1 of this Article.
7. Every citizen and resident with health difficulties is obliged to initially visit the family doctor, except in urgent cases.
8. Every citizen and resident should choose one family doctor.
9. Every citizen and resident has the right to choose and change the family doctor within the zone determined by the municipality.
10. Primary healthcare professionals collaborate with health professionals in secondary and tertiary healthcare in compliance with this law;
11. In order to increase the quality of healthcare services, primary level healthcare institutions shall ensure inter-sector cooperation with social welfare and education services, public security authorities and specific professional organizations, as well as with governmental and non-governmental humanitarian organizations.
12. Standards for organizing and functioning of the family medicine service shall be set by the sub-legal act from paragraph 1 of this Article.
13. In order to support the family medicine services, the Ministry shall supervise and regulate the integrated services of primary healthcare, in compliance with this law.

Article 19 **Secondary healthcare**

1. Secondary healthcare includes hospital, outpatient healthcare: diagnostic, therapeutic, rehabilitation, emergency transportation, and public healthcare.
2. Organization and activities of healthcare institutions from paragraph 1 of this Article are defined by a sub-legal acts issued by the Ministry.

Article 20 **Secondary healthcare in municipalities**

1. Secondary healthcare can be organized at the municipal level with the request of respective municipal assembly, as well, in compliance with the Decree of the Minister of Health.
2. Health care institutions that are not part of the health organization from Article 68 of this law in the municipalities where the secondary healthcare is implemented based on the relevant

legislation for local self government, shall have extended competencies to provide secondary healthcare, including: registration and licensing of health care institutions in cooperation with the Ministry, recruitment, payment of wages and salaries in compliance with the legislation into force, as well as training of health care personnel and administrators in cooperation with the chambers of health professionals from Article 78 of this Law.

3. Procedures for implementation of competencies in secondary healthcare are regulated by this law and relevant sub-legal acts, except if it is not determined differently by relevant legislation governing local administration.

Article 21 **Tertiary healthcare**

1. Tertiary healthcare is organized and provided in healthcare institutions licensed by the Ministry, providing besides health activities: university educational process, post-graduate, specialist and sub-specialist education and scientific-research work.

2. Tertiary healthcare includes advanced: inpatient, outpatient specialist healthcare and public health; consultancy services, and emergency transportation.

3. Institutions from the paragraph 1 of this Article should have a director for education and science appointed in cooperation with the relevant Faculty of Medical Sciences.

4. In healthcare institutions from the paragraph 1 of this Article the officials in leading positions of health professional units, beside specialist qualification, should also have academic degree of a professor, or in case of lack of degree of professor, he/she should have the doctor of science degree or higher professional education, as well as should have a full time job at these institutions.

5. Organization and implementation of the educational process in the institutions from the paragraph 1 of this Article is regulated by a sub-legal act issued by the Ministry of Health, the Ministry responsible for education and science, and the University of Prishtina, approved by the Government.

Article 22 **Educational process**

1. University education, specialist education, sub-specialist education, and continuous professional development can be offered in healthcare institutions at all three levels in compliance with the sub-legal act from paragraph 5 Article 21 of this law.

2. All health professionals with specialist qualification that have more than three (3) years experience of specialist work in institutions from paragraph 2. of this Article where the educational process is performed, are clinical mentors and receive financial compensation for their work, based on the sub-legal act from paragraph 1. of this Article as well as sub-legal act issued by the Ministry.

Article 23
Professional Healthcare Service

Professional healthcare services are organized with the aim to ensure continuity and integrity of healthcare services in specific field of health care, based on the specific sub-legal act issued by the Ministry.

Article 24
Referral to another healthcare institution

In cases when the healthcare institution is unable to provide healthcare within its scope, it is obliged to refer the citizen to other healthcare institutions able to treat the particular case accompanied with respective medical documentation, while respecting the referral system, from paragraph 3 Article 16 of this law.

CHAPTER VI
SPECIAL FORMS OF HEALTHCARE

Article 25
Private healthcare activities

1. Private activity in the health sector is regulated by this law and exercised on the basis of full equality with the public health sector, except cases otherwise provided in this law.
2. Health activities, not allowed in the private health sector includes:
 - 2.1. collection of blood and its derivatives;
 - 2.2. forensic medicine and autopsy services;
 - 2.3. epidemiology services (besides disinfection, disinsection and preventive deratization), human ecology, and environment microbiology.
3. Organization and functioning of the specific healthcare activity in the private health sector is regulated by sub-legal acts, issued by the Ministry.

Article 26
Pharmaceutical Sector

1. Medications at all levels of healthcare shall be prescribed with unprotected international nominations with exception of combined pharmaceutical products and medications with slow release of the active substance that may be prescribed with protected company name.
2. Medications prescribed by physician or a dentist can only be issued by or in the presence of licensed pharmacist.

3. The pharmaceutical sector is regulated based on specific laws.

Article 27
Public Health

Activity in the field of public health is regulated by the Public Health Law.

Article 28
Sanitary Inspectorate

The work, organization, authorizations, duties and competencies of the Sanitary Inspectorate are defined by a separate law.

Article 29
Occupational Health

1. Occupational Health is a special service of healthcare for workers, which is offered in the secondary and tertiary levels of healthcare.

2. Establishment, organization and activities of the occupational health services shall be defined in the sub-legal act issued by the Ministry.

Article 30
Blood and blood products

Collection, control, storage, distribution, and transfusion of blood and blood products are regulated by a special law.

Article 31
Protection from radioactive radiation, toxic and cancer inducing substances

Organization and activity of services for protection from radioactive radiation, toxic and cancer inducing substances, as well as the responsibilities related to this are set by specific laws.

Article 32
Psychoactive and narcotic substances

Manufacture, wholesale and retail sale, import, export, transit, transport, purchase, supply, sale, possession, consumption, use and dissemination of plants from which there can be obtained, narcotics, narcotic drugs, psychotropic substances and precursors are regulated by a special law.

Article 33
Sports medicine

1. Sports medicine is a form of organized healthcare for active sportsmen and citizens carrying out sport activities as recreation that is performed in secondary and tertiary level of healthcare.
2. Establishment, organization and activities of the Sport medicine service shall be defined in the sub-legal act issued by the Ministry.

Article 34
Physical and rehabilitation medicine

Physical and rehabilitation medicine is provided at the secondary and tertiary healthcare and shall be regulated with sub-legal act issued by the Ministry.

Article 35
Healthcare in prisons' services

1. Healthcare in prisons' services in the Republic of Kosovo is organized and functions as an integral part of the country's health system.
2. Services from paragraph 1. of this Article which functions in prisons that are under the authorities of the Ministry of Justice are organized and supervised by the Ministry of Health.
3. The healthcare from paragraph 1. of this Article is implemented in compliance with the sub-legal act issued by the Ministry of Health and the Ministry of Justice, approved by the Government.

Article 36
Healthcare in Kosovo Security Force and the Kosovo Police

1. Healthcare in Kosovo Security Force and the Kosovo Police is organized and functions as an integral part of the health system of the country.
2. Healthcare from paragraph 1 of this Article is implemented in compliance with the sub-legal act proposed by the Ministry, Ministry of Security Force of Kosovo and the Ministry of Internal Affairs, approved by the Government.

Article 37
Healthcare in the social care institutions

Healthcare measures in the social care institution are defined in the sub-legal act issued by the Ministry of Health and the respective ministry on social issues.

Article 38
Healthcare institutions in civil society

Healthcare services in the humanitarian healthcare institutions and other forms of the organized civil society within the field of healthcare are defined in the sub-legal act issued by the Ministry.

Article 39
Para-medical and alternative health treatment

1. Para-medical and alternative methods and procedures for treatment of diseases, disorders and injuries shall be registered, regulated and supervised based on the sub-legal act issued by the Ministry.
2. Methods and procedures from paragraph 1. of this Article that are not registered are prohibited.

CHAPTER VII
ESTABLISHMENT, LICENSING AND ACCREDITATION OF HEALTHCARE INSTITUTIONS

Article 40
Establishment

1. Natural persons and legal entities fulfilling the legal requirements can establish healthcare institutions.
2. A healthcare institution can be managed only by persons with relevant managerial skills and experiences.
3. Healthcare institution can be established in all organizational and ownership forms allowed by this law.

Article 41
Preventing the conflict of interest

1. It is prohibited to refer patients from a secondary and tertiary public healthcare institution to a private healthcare institution, for reasons that cannot be justified with medical arguments, regardless of the waiting list.
2. Any informal or formal financial or other type of award to the health professional employees in the public health sector including award for referral of the citizen or resident from public to private healthcare institution, and profitable relationship with pharmaceutical industry, is strictly prohibited.

3. Violators of the provisions of this Article will be subject to penalties or legal action as defined in this law and a special sub-legal act issued by the Ministry.

Article 42 **Licensing and Accreditation**

1. All healthcare institutions can begin work after being licensed by the Ministry or by a body authorized by it, in compliance with the sub-legal act issued by the Ministry defining the specific working conditions regarding: space, professional staff, and medical equipment.

2. Licensing of healthcare institutions shall be implemented in compliance with the plans, normative's and standards set by the Ministry.

3. Upon application for a license, the healthcare institution should deposit the act of establishment of the healthcare institution for which the Ministry has given its consent.

4. The body authorized by the Ministry makes the accreditation of healthcare institutions in accordance with the respective sub-legal act.

5. Accredited healthcare institutions have priority in contracting their services with the HFA.

6. In municipalities with enhanced competencies in provision of secondary health care licensing of these institutions shall be done in accordance with the respective legislation on local self-government and Article 20 of this law.

Article 43 **Change of Activity**

The provisions of this Law governing the licensing and commencement of work in healthcare institutions also apply in cases of change of activity of the healthcare institution.

Article 44 **Revocation of license**

1. Healthcare institution for which the authorized body has found that it has repeated the same violation more than two times in a row can have the license cancelled and the work terminated.

2. The order for termination of work of a healthcare institution from paragraph 1. of this Article is issued by the Ministry.

3. Health care institution which license have been revoked has the right to issue a justified complain to the Ministry, in compliance with the law.

Article 45
General Acts

1. The basic judiciary act of a healthcare institution is the statute.
2. The statute defines the healthcare institution's organization, the type of management, decision-taking and other issues related to implementation of healthcare and business affairs, in compliance with the law.
3. The healthcare institution may also issue other necessary regulations, which should be in compliance with the Statute.

CHAPTER VIII
SUPERVISION OF HEALTHCARE INSTITUTIONS

Article 46
Types of supervision

1. Regardless of the means of financing or the type of ownership all health care institutions, including the healthcare institutions from Article 20 of this Law shall be subject to both internal and external supervision.
2. The supervision from paragraph .1 of this Article shall ensure the application of respective legal provisions, professional and ethical norms, as well as contemporary standards in health.
3. Internal supervision from paragraph 1. of this Article includes internal audit and other bodies determined by legislation into force.
4. External supervision from paragraph 1. of this Article shall be applied by the Health Inspectorate, pharmaceutical Inspectorate, sanitary inspectorate, Auditor General of Kosovo, and other bodies determined by legislation into force.

Article 47
Inspectorates

1. Health Inspectorate is the administrative body of the Ministry.
2. Work, organization, authorizations, duties, and powers of the Health Inspectorate shall be determined by a special law.
3. Pharmaceutical Inspectorate is the administrative body of the Ministry.
4. Work, organization, authorizations, duties, and powers of the Pharmaceutical Inspectorate shall be determined by a special law.

5. Work, organization, authorizations, duties, and powers of the Sanitary Inspectorate shall be determined by a special law.

Article 48
Supervision on special forms of healthcare

Supervision of legal functioning of institutions from Articles 35, Articles 36, Articles 37 and Articles 38 of this law is ensured by the Ministry and the chambers of health professionals from Articles 78 of this law.

CHAPTER IX
HEALTH INFORMATION SYSTEM

Article 49
Unique and integrated system

1. The Ministry ensures establishment, development, and functioning of the unique and integrated health information system (hereinafter as HIS) .in the whole health sector, regardless of the type of healthcare institution, type of ownership, or organization, based on the normative's and standards set by the Ministry.

2. All healthcare institutions, responsible physical and juridical persons are obliged to collect health data and report them in the HIS, in compliance with the sub-legal act issued by the Ministry.

Article 50
Organization

1. The Ministry is responsible for financing and the operational functioning of the HIS.

2. The data on the health status of the population collected in HIS shall be accessible by the National Institute of Public Health for analysis and preparation of specific reports, in compliance with the sub-legal act from Article 49 paragraph 2. of this law.

3. Health Financing Agency (HFA) has access to the data in relation to health services collected in HIS, necessary for the conduct of its legal activity, prescribed by this law.

4. The organizational structure and functioning of HIS is regulated by a sub-legal act issued by the Ministry.

Article 51
Data collection and reporting

1. Types, content and management of the data; their collection, analysis and usage; as well as the reporting system within the unique HIS, are defined by the sub-legal act from paragraph 2. Article 49 of this law.
2. Health professional and healthcare institution shall report their services, not violating the rights of healthcare users and ensuring professional confidentiality in compliance with the law.
3. Each health professional, upon his signature, bears the responsibility for the accuracy of the data registered in the health documents and registers.

Article 52
Data ownership and responsibilities

1. Owner of the data is the healthcare institution entering the data, in compliance with the sub-legal from paragraph 2. Article 49 of this law.
2. Healthcare institution from paragraph 1 of this Article is responsible for:
 - 2.1. regular and safe, collection, storing, and management of the data;
 - 2.2. provision of the easy access to data;
 - 2.3. protection and confidentiality of the personal data; and
 - 2.4. protection of data from abuse, in compliance with the legislation in power.

Article 53
Access

1. Access, the level of access, and authorization of access to HIS is defined by the Ministry in compliance with the sub-legal act from paragraph 2. Article 49 of this law.
2. In order to ensure continuity of treatment, healthcare institutions are obliged to provide access to respective electronic data or when they don't exist to inform in written healthcare institution to where the user of health care services has been referred for diagnosing, treatment, or rehabilitation.

Article 54
Supervision

Coordination and supervision of functioning of HIS is implemented by the Ministry in compliance with the sub-legal act from paragraph 2. Article 49 of this law.

CHAPTER X HEALTHCARE FINANCING

Article 55 The Healthcare Financing System

1. Financing of healthcare in the Republic of Kosovo is going to be done through a mixed model of financing by the budget and the health insurance system, public and private.
2. Health Insurance Fund as part of the public health insurance system referred to in paragraph 1. of this Article can only be established and regulated by a special law.

Article 56 Health Financing Agency

1. Health Financing Agency (HFA) is an executive agency of the Ministry, which realizes the rights, obligations, responsibilities, and authorizations with respect to the negotiation and contracting services from the List of health care services and List of drugs and medical consumables material from health institutions licensed in all forms of ownership, as well as the collection of all funds for this purpose.
2. Priority when contracting health services shall be to the accredited health institutions.
3. HFA sets the performance stimulation scheme of health professionals and relevant professional services at all three (3) levels of health care, based on objective and transparent criteria to meet the volume and quality indicators of health care services provided by sub-legal issue by the Ministry.
4. Establishment, organization, modalities of contracting, and the overall functioning of HFA shall be regulated by sub-legal act issued by the Government.

Article 57 The Means for Healthcare Financing

1. Financial means required for funding of the healthcare services from sub-paragraph 1.26. Article 3 of this law, shall be provided from resources, as follows:
 - 1.1. budget of Kosovo;
 - 1.2. municipal budget;
 - 1.3. co-payments from users of healthcare services who are not exempted, in compliance with this law;
 - 1.4. gifts and legacies form individual citizens;
 - 1.5. donations, in cash or similar;

1.6. incomes from authorized activities;

1.7. health insurance institutions, local and foreign, private and public (upon its establishment, in compliance with this law);

1.8. direct payments by users and by health insurance institutions, local and foreign, private and public (upon its establishment), in compliance with this law.

Article 58

Copayments

Copayments shall be regulated by a sub-legal act issued by the Ministry and can be changed at any time.

Article 59

Basic healthcare services

1. Basic health care services covered by the HFA, shall be defined in the service List prepared by the technical committee appointed by the Minister of Health at the beginning of each fiscal year; approved by the Government, in accordance with available financial resources and health needs of the population.

2. List referred to in paragraph 1. of this Article shall be submitted to HFA along with the financial statement on the possibilities for financial coverage of the proposed package of services.

3. Basic healthcare services are provided in licensed health institutions, public and private, as well as within the public-private partnership, in the three (3) levels of healthcare, with which HFA has signed a contract.

4. Reimbursement of drugs and medical consumables shall be done only when the drug has been described by family medicine service in official prescription and generic name.

5. Additional healthcare services that are not part of the List in paragraph 1. of this Article shall be provided upon payment of health insurance premium in the private health insurance companies in the country or public and private abroad or by direct payment of the price of the service in the health institution.

Article 60

Financing healthcare institutions

1. Healthcare institutions, physical and juridical persons exercising healthcare activities are obliged, for each patient, to document the cost as well as the type, the volume, the quality and the price of health services.

2. Healthcare institutions and organizations receiving public funds for implementation of healthcare are obliged to keep accounts and records based on the law, and to provide the necessary information to the authorized bodies.

Article 61

Citizens and residents exempted from copayments

1. Citizens exempted from copayments are those persons with an income under the official social vulnerable line established by the Government, in categories of the registered individuals as socially vulnerable or poor based on the sub-legal act issued by the Ministry of Health and the Ministry of Labor and Social Welfare.

2. Citizens exempted from copayments are also persons who are:

2.1. victims of trafficking during first year after official registration, in compliance with the law;

2.2. habitual residents of informal settlements in the Republic of Kosovo who are not registered or who are undergoing the registration process until the registration process is completed or for one (1) year after this law enters into effect, whichever happens earlier;

2.3. repatriated persons based on the bilateral agreement for repatriation between the Republic of Kosovo and other countries, in the first year after repatriation;

2.4. prisoners during their sentence in jail;

2.5. forcibly displaced persons out of their homes as a victim of domestic violence during first year after official registration at the Ministry of Labor and Social Welfare, in compliance with the law;

2.6. blood donors that possess relevant proof issued by the Kosovo Blood Transfusion Agency that they have donated blood at least five (5) times in the last two (2) years.

3. Service costs from List of healthcare services to the citizens and residents of paragraph 1. and paragraph 2. of this Article shall be transferred by the Government through respective budgetary transfers at HFA, upon the request of the Ministry, the medium-term expenditure framework and legislation into force.

CHAPTER XI
HOSPITAL AND UNIVERSITY CLINICAL SERVICE OF KOSOVO

Article 62
Hospital and University Clinical Service of Kosovo

1. Hospital and University Clinical Service of Kosovo (hereinafter HUCSK) shall be established as a health institution, with a special public importance, with residence in Prishtina.
2. HUCSK consists of secondary and tertiary level healthcare institutions in the public health sector, defined by sub-legal act issued by the Ministry in accordance with the law.
3. HUCSK has legal autonomy of the legal person with rights, obligations, and responsibilities specific to the implementation of this law and sub-legal acts issued by the Ministry.
4. In legal operation HUCSK obtains the rights and obligations, is owner of movable and immovable assets relating to its health activity, and is a party to proceedings before courts or other state bodies.
5. HUCSK shall exercise activities and fulfill its obligations and duties in accordance with the norms, standards, strategies and policies issued by the Ministry.
6. The employees at HUCSK do not belong to civil service of Kosovo.

Article 63
Establishment of Hospital and University Clinical Service of Kosovo

1. HUCSK shall be established by this Law.
2. The basic act of HUCSK is the Statute, approved by the Government upon the proposal of the Minister of Health.
3. By the Statute of HUCSK shall be determined: the number of constituent units, their authorizations, scope, organization, function, rights, duties, responsibilities and ways of performing activities under this law.

Article 64
Management of Hospital and University Clinical Service of Kosovo

1. HUCSK shall be managed by the Managing Board.
2. The Managing Board is the highest decision-making body of HUCSK.
3. The Managing Board shall consist of seven (7) members:
 - 3.1. one (1) representative from the University Clinical Center of Kosovo;

- 3.2. one (1) representative from the Dental University Clinical Center of Kosovo;
 - 3.3. one (1) representative from the National Institute of Public Health;
 - 3.4. one (1) representative from regional hospitals, on rotation basis and fulfillment of health service quality indicators;
 - 3.5 one (1) representative from the primary health care services, based on the proposal of the Association of Municipalities of the Republic of Kosovo;
 - 3.6. one (1) representative from the Ministry of Health;
 - 3.7. one (1) health management expert with high scientific and professional qualifications selected by a public announcement.
4. The Managing Board shall be appointed by the Government on the proposal of the Minister of Health.
 5. The Managing Board responds to the Government through the Minister of Health.
 6. Mandate of the Managing Board members lasts three (3) years.
 7. The Managing Board shall be headed by the Chair for a term of one (1) year who is elected based on the principle of rotation of its members.
 8. The Managing Board may appoint as an observer national or international experts to support its work in relation to specific issues.
 9. Scope, authorizations, decision-making and responsibility of the Managing Board shall be determined by the act on the establishment and Statute of HUCSK.
 10. Operational affairs of HUCSK shall be managed by the General Director appointed by the Managing Board based on a public announcement.
 11. General Director of HUCSK shall be appointed for a period of three (3) years.
 12. General Director of HUCSK is responsible for professional performance and financial business of HUCSK.
 13. Scope, authorizations and responsibilities of the General Director shall be determined by Charter of HUCSK.

Article 65
Financing the Hospital and University Clinical Service of Kosovo

1. HUCSK shall be funded by the Kosovo budget and other resources provided by the law, applicable legislation and sub-legal acts issued by the Ministry.

2. HUSCK Funding shall be applicable according to the Law on Public Finance Management and Accountability.
3. If during the course of its activities HUSCK realizes profit, and such profit can only be used to improve the performance of its health activities and can not be used for other purposes.
4. In the event of adverse business financial, HUSCK can not attribute the eventual losses to the Ministry or the Government of the Republic of Kosovo.
5. List of services and price list of services offered by HUSCK shall be approved by the Board of List of services and price list of services offered by SHSKUK approved by the Board of SHSKUK.
6. Services from paragraph 1. of this Article in HUSCK may be used as in following:
 - 6.1. citizens and residents as defined in Article 59 of this law will use these free services;
 - 6.2. all citizens and other residents will use these services by participating in treatment costs through co-payments whose value will be determined by sub-legal act issued by the Ministry, in accordance with Article 58 of this Law;
 - 6.3. citizens and residents who are customers of foreign companies (private or public), or local (private) of health insurances will use these services based on their status documented health insurance.

Article 66
Supervision of the Hospital and University Clinical Service of Kosovo

1. Supervision of the HUSCK activities shall be conducted by the Ministry and the Government of Kosovo.
2. To ensure supervision of HUSCK, Ministry and Government shall:
 - 2.1. supervise activities and legality of HUSCK works;
 - 2.2. require and review regular annual and quarterly reports with financial statement, audit reports; and additional reports on the activities of the HUSCK Management Board;
 - 2.3. undertake other measures defined by the Law.
3. The Hospital and University Clinical Service of Kosovo shall:
 - 3.1. prepare Annual Report and periodic reports quarterly on its activities to the Ministry, and the Government;

- 3.2. prepare annual report and additional reports and presents its activity at the request of the Government and its bodies;
- 3.3. prepare other significant information.

Article 67

Control and Audit of the Hospital and University Clinical Service of Kosovo

1. HUSCK shall be subject of internal and external auditing procedures, in accordance with the law.
2. In cases where there is a suspicion that there is a violation of legislation or failure to perform duties by the Managing Board of HUSCK, Director General, or its component parts, the Minister of Health may at any time request the performance of audit of the HUSCK by the Office of the Auditor General.
3. In the event that the audit report confirms legal violation or suspicion based on paragraph 2. of this Article, the Minister of Health may require the suspension of the Governing Board and shall initiate procedures for the appointment of a new Board in accordance with Article 64 of this Law.

Article 68

1. List and price list of services offered by HUSCK proposed by the HUSCK Board of Directors and shall be approved by the Agency for Health Financing in the Ministry of Health.
2. Services referred to in paragraph 1. of this Article in HUSCK can be used as follows:
 - 2.1. citizens and residents referred to in Article 61 of this law shall use these services without payment;
 - 2.2. all citizens and other residents will take use these services by participating in treatment costs through co-payments whose value will be determined by sub-legal act issued by the Ministry, in accordance with Article 58 of this Law;
 - 2.3. citizens and residents who are customers of foreign companies (private or public), or local (private) of health insurances will use these services based on their status documented health insurance.
3. HUSCK shall be financed and operates in accordance with this Law, applicable legislation and sub-legal act issued by the Ministry.

CHAPTER XII HEALTH PROFESSIONALS

Article 69 Profiles

1. Profiles of health professionals are the following:

- 1.1. Doctor of medicine, doctor of dentistry (specialist, sub-specialist);
- 1.2. Graduated Pharmacist, Master of pharmacy (specialist; sub-specialist);
- 1.3. Clinical psychologist, (specialist, subspecialist);
- 1.4. Graduated nurse;
- 1.5. Graduated physiotherapist;
- 1.6. Graduated midwife;
- 1.7. High medical laboratory technician;
- 1.8. Graduated logopedist;
- 1.9. Graduated audiologist;
- 1.10. Graduated phoniatriest;
- 1.11. Medical professionals with a middle or high education, as defined in the official register of the Ministry of Health;
- 1.12. Other professional associates with non-medical education, registered in the official register by the decision of the Minister of Health, at the proposal of the respective Chamber of Health Professionals from Article 78 of this law.

Article 70 Apprenticeship and professional exam

After the completion of the relevant educational level, obligatory apprenticeship and professional exam for all categories of the health professionals should be implemented in compliance with a sub-legal act issued by the Ministry.

Article 71 Licensing

1. Following the successful completion of the professional exam, the health professional should be registered in the chamber of health professionals from Article 78 of this law.

2. Licensing of the health professional is done by the respective chamber of health professionals, in compliance with this law.
3. Health professionals can provide health services independently only after obtaining the license.
4. Licensing of foreign health professionals is defined by a sub-legal act proposed by the Ministry and approved by the Government.
5. After licensing from paragraph 2. of this Article, health professional that decides to work in the family medicine ambulances in rural areas shall be immediately employed as a part of family medicine services for the period of two (2) years.
6. Necessary financial means for implementation of the paragraph 5. of this Article shall be provided by the Ministry.

Article 72

Specializations

1. Licensed health professionals with university degree have the right to further professional education in different fields of the healthcare, through specialist post-graduate education - specialization.
2. The respective Ministry for Education and Science is responsible for recognition of university diplomas in the field of medicine obtained outside Kosovo.
3. The Ministry, based on the proposal of the chamber of health professionals is responsible for recognition of medical specialization obtained outside Kosovo.
4. Planning, implementation, and financing of the specialization is the responsibility of the public, private, or public-private healthcare institution, licensed by the Ministry for this purpose, in compliance with the sub-legal act, issued by the Ministry.
5. The chamber of health professionals shall conduct the verification of the legitimacy of the specialization process and shall organize the specialist exam.
6. The Minister of Health shall sign the specialization diplomas.
7. In order to improve the quality of work at the all three levels of healthcare, specialists, licensed specialists that have finished specialistic education based on the contract with the Ministry and has been licensed shall be employed through a special program of the Ministry for the period of three (3) years.

Article 73

Specialization for foreign citizens

Specializations for foreign citizens shall be organized based on the sub-legal act issued by the Ministry.

Article 74
Sub-specializations

1. After licensing as a specialist, the health professional has the right to be qualified in different areas of healthcare through sub-specialist education.
2. The Chamber of Health Professionals shall organize and supervise sub-specializations, from Article 78 of this law.
3. The Ministry, on the proposal of the Chamber of Health Professionals shall verify the sub-specialization diplomas.
4. Planning, implementation, and financing of the sub-specialization is the responsibility of the public, private, or public-private healthcare institution, licensed by the Ministry for this purpose, in compliance with the sub-legal act.
5. The chamber of health professionals shall conduct the verification of the legislation of the sub-specialization process and organize the sub-specialist exam.
6. The Minister of Health shall sign the sub-specialization diplomas.

Article 75
Continuous Professional Development

1. Health professionals are obligated to participate in continuous professional development with the goal to maintain and enhance their professional qualifications.
2. All healthcare institutions are obliged to provide conditions for continuous professional education of their health professionals, in compliance with this law and the general acts of the institutions.
3. Continuous professional development is documented by the Continual Medical Education (CME) Credits, registered in the personal portfolio.
4. The number of CME credits, types of trainings, eligibility of institutions to provide CME credits, and other relevant issues for continuous professional development shall be under the authority of the respective chamber of health professionals from Article 78 of this law.

Article 76
Re-licensing

The number of CME credits required for re-licensing and other standards and norms shall be defined by the respective chamber of health professionals, in compliance with the law.

Article 77
The rights and responsibilities of healthcare professionals

The rights and responsibilities of healthcare professionals and their working conditions are regulated by this law, the Labor Law, and the other legal acts in power.

CHAPTER XIII
CHAMBER OF HEALTH PROFESSIONALS

Article 78

1. The chambers of health professionals are professional organizations established by the Kosovo Assembly.
2. The chambers from paragraph 1. of this Article, are organized in the fields of medicine, dentistry, pharmacy, and nursing, and regularly inform the Ministry about their work.
3. All health professionals should be members of the respective chamber from paragraph 2. of this Article.
4. The chambers of health professionals carry out self-regulations and professional supervision on the work, training, and continual professional development of health professionals.
5. The chambers of health professionals shall be self – financed by membership fees and other forms of payments of the health professionals from paragraph 3. of this Article, in accordance with the law from paragraph 1 of this article.

CHAPTER XIV
THE RIGHT ON STRIKE

Article 79

All health professionals employed in healthcare institutions have the right to strike, in compliance with the legislation in power.

Article 80
Obligations during the strike

1. During strike, all healthcare institutions should at a minimum provide minimal working process, ensuring prevention of any mitigation of the health status of healthcare service users, including:
 - 1.1. continuous and unobstructed vaccinations according to the envisaged plans;

1.2. implementation of hygienic-epidemiologic measures in case of risk of epidemics, respectively during its term;

1.3. diagnosing and urgent treatment, giving therapies, giving blood and its products and transportation of health service users with emergent diseases or disorders.

Article 81

Staff working with or which work is a precondition for the functioning of emergency care services are not allowed to strike.

CHAPTER XV DEATH

Article 82 Conclusion about death

1. For every citizen who is supposed dead, the death conclusion should be ascertained by the doctor.
2. The time and cause of death should be reported in the death form.
3. The death certificate cannot be issued if the dead is buried without respecting the paragraph 1. of this Article.
4. The healthcare institution shall be responsible to ascertain the cause of the death in the healthcare institution.
5. The cause of the death for persons that pass away outside healthcare institutions should be ascertained within twelve (12) hours after receiving information about the incident.
6. The Sanitary Inspectorate and the Kosovo Police must be informed if a person has passed away due to a contagious disease.
7. Kosovo Police and the prosecutor must be informed if a person has died in a violent manner.
8. If death has happened in prison and the person was imprisoned the respective court and the family of the dead, shall be informed.

Article 83 Determination of the cause of death

1. The cause of the death shall be defined either through a normal dead examination, clinical autopsy, or a forensic autopsy.

2. Clinical autopsy is mandatory in cases when:

2.1. the cause of death is unclear;

2.2. the health professional who have treated the citizen before death, makes an official request and has the family consent;

2.3. the health inspectorate makes an official request;

2.4. the close family member or his legal representative makes an official request;

2.5. the death has happened in prison;

2.6. the death has happened during prosecution procedures.

3. The expenses of the clinical abduction from paragraph 2. of this Article are covered by the legal or physical person obliged by this law to pay the expenses of treating the citizen.

4. The expenses of the clinical abduction required by an official institution are covered by that respective institution.

5. The cause of violent death is ascertained by the forensic abduction requested by the prosecutor or the court, in compliance with law.

CHAPTER XVI CLINICAL RESEARCH ON HUMANS

Article 84

1. No clinical research on humans can be conducted without the approval of the research by a professional body authorized by the Minister of Health.

2. Issues related to clinical research on humans shall be defined by a special law.

CHAPTER XVII TERMINATION OF PREGNANCY AND ARTIFICIAL STERILIZATION

Article 85

1. Termination of pregnancy is not allowed after the tenth week of pregnancy, except under conditions from paragraph 2. of this Article.

2. Termination of pregnancy after the tenth week is possible only if there are serious health implications for the mother or/and the baby, or when pregnancy is the result of rape or incest certificated by authorized legal authorities.
3. The medical implications mentioned in paragraph 2. of this article should be defined by a committee consisting of three (3) medical specialists: two (2) gynecologists-obstetricians and one (1) psychiatrist.
4. Termination of pregnancy is regulated by a special law.

Article 86 Artificial sterilization

1. Artificial sterilization can be carried out at the individual request of both genders after medical consultation.
2. Artificial sterilization can also be carried out in cases where the patient's health is endangered according to the recommendation of a specialist doctor and with the written consent of the patient.
3. If the written consent from paragraph 2. of this Article cannot be provided, provisions of the Law on the Rights and Responsibilities of the Citizens in Healthcare from paragraph 5. Article 4, shall be applied.

Article 87 Assisted Fertilization

1. Assisted fertilizing, is prohibited in cases the sexual cells of the person are used without his knowledge and if it is used to fertilize another person than the couple with or without his knowledge.
2. Artificial fertilizing is not allowed, in cases when the donor is a close family member of one of the members of the couple.
3. Assisted fertilization is applied according to the provisions of the sub-legal act issued by the Ministry.

CHAPTER XVIII CELL, TISSUE, AND ORGAN TRANSPLANTATION

Article 88

1. All advertisement, bargaining, and illegal trafficking related to transplants, are prohibited.

2. Cell, tissue and organ transplantation shall be carried out only in a healthcare institution authorized for this purpose by the Ministry.
3. Cell, tissue and organ transplantation is regulated by a special law.

CHAPTER XIX HEALTHCARE DURING EMERGENCIES

Article 89 Responsibilities of the Ministry

1. During the state of emergency, the provision of healthcare is ensured by the Ministry in compliance with the law and other legislations in power.
2. Healthcare activities in case of emergencies from paragraph 1. of this Article include:
 - 2.1. the implementation of legal provisions in force;
 - 2.2. adapting the healthcare system in compliance with the emergent planning;
 - 2.3. implementing changes within referral and management system;
 - 2.4. provision of emergency healthcare for citizens;
 - 2.5. functioning of the provisional healthcare institutions;
 - 2.6. activating supplementary and reserve resources.
3. During emergency situations, the citizens' rights defined by the law shall be guaranteed to an extent that will not endanger the efficiency of efforts undertaken to overcome the emergency situation.
4. The human dignity shall in general be respected, regardless of the limitations from paragraph 3 of this Article.

Article 90 Responsibilities of the Government

1. The Government organizes, prepares and finances activities for implementation of healthcare activities during emergencies.
2. Preparatory activities of the Government for healthcare provision in emergencies include:
 - 2.1. provision of planning activities;
 - 2.2. determining managerial structures;

- 2.3. determining the obligation for cooperation between sector and municipal authorities;
- 2.4. development of legal and administrative regulations;
- 2.5. ensuring stocks of drugs and medicinal expendables;
- 2.6. renewal of the state healthcare reserves to the level necessary;
- 2.7. ensuring training for implementation of the healthcare in states of emergency.

Article 91
Responsibilities of healthcare institutions

1. Healthcare institutions are obliged to develop plans for states of emergency.
2. The formal conditions for such plans from paragraph 1. of this Article shall be defined in the sub-legal act issued by the Ministry.

CHAPTER XX
PROVISIONS REGULATING INTERNATIONAL RELATIONS

Article 92

1. Healthcare provision in the public healthcare institutions to non-Kosovar citizens residing in Kosovo, as well as compensation for provided services shall be made on the grounds of: legislation in power, interstate agreements, international agreements, or based on the principle of reciprocity, following EU Regulations 883/04 and 987/09.
2. In the absence of legal conditions from paragraph 1. of this Article, foreign citizens are obliged to healthcare in the territory of the Republic of Kosovo, based on the provisions of this law.
3. For foreign citizens that seek emergency healthcare, this care should be provided under the same conditions as for the citizens of the Republic of Kosovo.
4. The cause and circumstances of the death of non-Kosovo citizens should be ascertained, in compliance with this law.
5. In the case of death of a foreign citizen, the competent international bodies should be notified immediately.
6. Participation in healthcare service provision or other forms of international cooperation in the health field, in cases of a state of emergency outside the territory of the Republic of Kosovo is realized based on international agreements or based on the principle of reciprocity.

CHAPTER XXI DISCIPLINARY AND COURT PROVISIONS

Article 93 Written notice

1. The healthcare institution shall be given a written notice by the Health Inspectorate in cases of:

- 1.1. essential violation of the code of medical ethics;
- 1.2. essential violation of norms from technical and medical safety;
- 1.3. violation of obligations during strikes;
- 1.4. mistakes during the process of treatment;
- 1.5. non-compliance with the conditions and non-application of measures of healthcare;
- 1.6. miss-conduct of citizens.

2. The healthcare institution and its director not complying with the written notice are subject to punitive measures defined by Article 94 of this law.

Article 94 Sanctions for Administrative Offenses

1. A fine of two thousand (2.000) up to eight thousand (8.000) € shall be the charge of healthcare institution in cases of administrative offences when the institution:

- 1.1. conducts activities without fulfilling the conditions of Article 40 of this law;
- 1.2. violates provisions of paragraph 3. Article 41. of this law, conducting illegal referral of healthcare user;
- 1.3. conducts activities against paragraph 1. Article 42 of this law, without a valid working license;
- 1.4. does not keep medical records and evidences of the healthcare user in compliance with Article 52 of this law;
- 1.5. fails to ensure access to health data in compliance with paragraph 1. Article 53 of this law;
- 1.6. fails to ensure the death conclusion and the cause of death according to paragraph 4. Article 82 of this law;

- 1.7. fails to ensure conditions for continuous professional development of health professionals hired by the institution, in compliance with Article 75 of this law;
 - 1.8. fails to ensure healthcare during strike, from Article 80 and Article 81 of this law;
 - 1.9. fails to harmonize the organization and normative acts with this law, as defined in Article 96 of this law;
 - 1.10. does not provide terms for supervision or prevents the authorized body from Article 47 of this law, to carry out its duty, in compliance with the law;
 - 1.11. does not obey on the written notice.
2. The person in charge of the healthcare institution shall be punished by the fine of two thousand (2.000) Euros up to five thousand (5.000) Euros for violation of provisions from:
- 2.1. Article 40 and 42 for conducting activities without fulfilling the legal conditions set by this law;
 - 2.2. Article 41 of this law on prevention of conflict of interest;
 - 2.3. Article 52 of this law on protection of data of the healthcare user;
 - 2.4. paragraph 1. Article 53 of this law, for not ensuring the legal access to health data;
 - 2.5. Article 68 of this law on continuous professional development;
 - 2.6. Article 80 and Article 81 of this law on provision of healthcare during the strike;
 - 2.7. paragraph 4. Article 82 of this law on death conclusion;
 - 2.8. paragraph 2. Article 83 of this law, on death conclusion with abduction;
 - 2.9. Article 96 of this law on harmonization of organization and normative acts with this law.
3. Health professional shall be punished by revocation of license in a time span of:
- 3.1. six (6) months upon violation of provisions in paragraph 1. Article 41 of this law on illegal referral;
 - 3.2. one (1) year upon violation of provisions in paragraph 2. Article 41 of this law by receiving illegal financial or other award;
 - 3.3. six (6) months upon violation of provisions in paragraph 2. Article 51 of this law by not reporting the data in compliance with this law;
4. Health professional shall be punished by the fine of one thousand (1000) Euros up to two thousand (2000) Euros in cases when he:

- 4.1. undertakes treatment without consent of the citizen or resident or his authorized representative, violating provisions of the sub-legal act from Article 4 of this law with the exception of the emergent cases when their lives are at risk;
 - 4.2. offers medication for the citizen or resident without the receipt against the provisions in paragraph 2. Article 26 of this law;
 - 4.3. exercises healthcare activities without a valid working license, contrary with paragraph 3. Article 71 of this law;
 - 4.4. exercises healthcare violating ethical and professional principles;
 - 4.5. offers the medicament for the healthcare user without a receipt, against paragraph 2. Article 62 of this law.
 - 4.6. implements fees for services, violating approved price-list.
5. Funds collected by fines are income of the Kosovo Budget in compliance with the legislation in force.

Article 95
Work prohibition of the healthcare institution

1. Healthcare institution is punished with revocation of license in the time span of one (1) year in the following cases:
 - 1.1. violation of provisions in paragraph 2. Article 41 of this law, by giving illegal awards to the health professionals;
 - 1.2. violation of paragraph 2. Article 49 of this law, by not ensuring the data for HIS, as set by this law;
 - 1.3. violation of paragraph 3. Article 71 of this law, by providing possibility for health professionals to practice without a valid working license.
2. The healthcare institution at which continuously there are ascertained irregularities by the authorized organ from Article 47 of this law is prohibited to work.
3. The decision of seize the work of a healthcare institution from paragraph 1. and paragraph 2. of this Article shall be issued by the Ministry.
4. The healthcare institution from paragraph 2. of this Article has the right on appeal in compliance with the law.

CHAPTER XXII INTERIM AND FINAL PROVISIONS

Article 96

1. Healthcare institutions, other juridical and physical entities exercising healthcare activities in compliance with this Law, shall harmonize the organization, work and their general acts with the provisions of this Law within six (6) months from the day this law enters into force.
2. Procedures for renewal and obtaining the work license of health institutions as well as performing specializations initiated under Law on Health 2004/4, Law No.03/L-124 Law on Amending and Supplementing the Law on Health; Law on Private Activities at Health No. 2004/50 and sub-legal acts adopted on the basis thereof, until the day of entry into force of this Law shall be completed according to these legal acts.

Article 97

Until the functioning of the HIS, the Ministry is responsible for collection of the necessary data for developing, supervision, and implementation of health policies and strategies.

Article 98

The Ministry ensures the enforcement of the duties and competencies of the chamber of health professionals, from Article 78 of this law until they are established and functioning.

Article 99

1. The contracting of services with providers will only be initiated after:
 - 1.1.the list of covered services is defined;
 - 1.2.the price for each item in the list has been set;
 - 1.3.the volume of covered services has been agreed;
 - 1.4.the total cost of covered services has been calculated and;
 - 1.5.the financing means have been allocated within the budget allocation (after accounting for co-payment income).
2. The list of drugs and medical consumables shall be defined and enter into force only after their fiscal impact has been assessed and the financing means have been allocated within the budget allocation (after accounting for co-payment income).

Article 100

The Government and the Ministry within one (1) year from the entry into force of this Law shall issue sub-legal acts, foreseen by this Law.

Article 101

When entering into force, this law shall supersede the Law on Health No. 2004/4; Law No. 03/L-124 on amending and supplementing the Health Law, the Law on Private Healthcare Services No. 2004/50 and legal provisions in contradiction with this law.

Article 102

This law shall enter into force fifteen (15) days after publication in the Official Gazette of the Republic of Kosovo.

Law No. 04/L-125
13 December 2012

President of the Assembly of the Republic of Kosovo

Jakup KRASNIQI