

**On public health and health care system**

***Non-official translation***

The Code of the Republic of Kazakhstan dated on September 18, 2009 No 193-IV

Unofficial translation

      The order of enforcement of the Code of the Republic of Kazakhstan, see Art. 186

 **GENERAL PART**

 **SECTION 1. GENERAL PROVISIONS**

 **Chapter 1. BASIC PROVISIONS**

**Article 1. Basic terms used in this Code**

      1. The following basic terms shall be used in this Code:

      1) human environment (hereinafter - the environment) - a set of natural, human and social factors, environmental (natural and artificial), defining the conditions of human life;

      2) HIV - human immunodeficiency virus;

      3) an anonymous examination – a voluntary medical examination of a person without his identification;

      4) emergency medicine - a branch of medicine and healthcare, aimed at prevention and elimination of medical-healthcare consequences of natural and man-made disasters, including prevention and medical treatment of population, sanitation and anti-epidemic (preventive) measures, protection and rehabilitation of health of those, involved in emergency situation liquidation and medical assistance for rescuers;

      5) potentially dangerous chemical and biological substances – the substances, which, under certain conditions and in certain concentrations, can be harmful to human health or the future generation, application and use of which shall be regulated by the legal acts on healthcare and epidemiological safety and health standards;

      6) military medicine - the branch of medicine and health care, a system of scientific knowledge (a set of scientific and practical subjects) and practical military medical service, aimed at comprehensive medical support of troops in peace and wartime;

      7) military medical care – the medical care, provided by the specialists of military medical services to the military servants and those, injured by combat weapons;

      8) military medical service - a set of military healthcare (medical) units, in which the laws of the Republic of Kazakhstan provide for military or special service, designed for medical support of these bodies;

      9) military-medical (medical) subdivisions:

      structural subdivisions of central executive authorities and other central government bodies, organizing and coordinating the military-medical (medical) institutions’ (organizations’) activity;

      military-medical (medical) institutions (organizations) and other subdivisions of the central executive authorities and other central government agencies, providing military-medical care to the appropriate contingent;

      10) military-medical (medical) supply - a set of actions for logistics and organization of medical care in military units, departments and departmental organizations in order to restore the combat capability and power of the staff;

      11) a child - a person under eighteen (the age of majority);

      12) irreversible brain death – a complete loss of integral function of brain cells, accompanied by the death of the brain substance;

      13) a profile specialist – a medical specialist with higher medical education, having a certificate for a particular qualification;

      14) biologically active substances – the substances of different origin, normalizing the diseased body functions in humans and animals that are the potential sources for medicines production;

      15) biologically active supplements – the supplements to the products, designed to improve health under condition of regular drug use and containing the components of natural or identical to natural biologically active substances in order to enrich a diet of a person;

      16) an original drug - the drug, containing the new active substances;

      16-1) hemopoietic stem cells – cells of a bone marrow of a person, being able to a differentiation;

      17) genetically modified objects – the raw materials and plant and (or) animal products, manufactured with the genetic engineering techniques, including genetically modified sources, organisms;

      18) drugs – the substances, containing pharmacologically active substances, designed to prevent, diagnose and treat diseases, and to change the status and functions of the body: the drug substance, medicinal raw material of natural origin, medical bulk products, medicines, medical immunobiological drugs, parapharmaceuticals;

      19) a single distributor for purchasing and providing drugs, medical products - a legal entity, which, in the frames of the guaranteed volume of free medical care, organizes the purchase, conclusion of supply contracts with suppliers, as well as the storage and delivery of medicines and medical products to customers;

      20) retail sales of pharmaceuticals, medical supplies and medical equipment – the pharmaceutical activity, related to acquisition (excluding import), storage, distribution, selling (excluding export) to the end user and destruction, carried out in accordance with the regulations, adopted by the Government of the Republic of Kazakhstan;

      21) wholesale of pharmaceuticals, medical supplies and medical equipment – the pharmaceutical activity, related to procurement, storage, import, export, selling (except for selling medicines to the population) without volume limits, and destruction, carried out in accordance with the regulations, adopted by the Government of the Republic of Kazakhstan;

      22) circulation of medicinal products, medical supplies and medical equipment – the activity, aimed at bringing of safe, effective and quality medicines, medical supplies and medical equipment from the developer and (or) manufacturer to the consumer;

      23) the objects, involved in circulation of medicines, medical supplies and medical equipment – a drugstore, pharmacy in health care organizations, providing primary health care, consultative and diagnostic services, a mobile pharmacy in remote rural areas, a drug store, a warehouse for temporary storage of drugs, medical supplies and medical equipment, an optical shop, a store of medical equipment and medical supplies, a storage of medical equipment and medical supplies, an organization for production of medicines, medical supplies and medical equipment, working in accordance with the standard provisions, approved by the Government of the Republic of Kazakhstan;

      24) subjects, involved in circulation of drugs, medical supplies and medical equipment – the individual persons or legal entities, engaged in pharmaceutical activities;

      25) State register of drugs, medical supplies and medical equipment – the accounting document for drugs, medical supplies and medical equipment, that are registered and approved for medical use in the Republic of Kazakhstan;

      26) bulk drug products – a dosed drug that has passed all stages of technological process, except for the final packaging;

      27) the expiration date of a drug - the date after which the drug is not applicable;

      28) packaging of a drug - a device or a set of tools, providing circulation of drugs via protecting them from damage and loss, as well as protecting the environment from pollution;

      29) quality of pharmaceuticals, medical devices and medical equipment – a set of properties and characteristics of a drug, medical device and medical equipment, affecting their ability to operate as intended;

      30) an international non-proprietary name of a drug - the name of the drug recommended by the World Health Organization;

      31) a drug – a drug in a certain dosage form;

      32) manufacturing of drugs - the pharmaceutical activities, related to manufacturing of medicines in drug stores, as well as acquisition of drug substances, storage, quality control, design and selling of the produced medicines;

      33) a medicinal form – a list of medicines, approved by the head of healthcare organization and coordinated in the order, defined by the authorized body in healthcare area, formed to provide a guaranteed volume of free medical care, taking into account the profile of the health care organization, the sufficient amount of which is obligatory;

      34) traditional medicine - a branch of medicine and activity of health workers, based on the accumulated public methods and means of prevention and treatment of disease, established in the old traditions of medical practice;

      35) health - a state of complete physical, mental (psychological) and social welfare and not only absence of disease or physical disabilities;

      36) health care - a system of political, economic, legal, social, cultural, and medical measures, aimed at prevention and treatment of diseases, maintenance of public hygiene and sanitation, saving and strengthening of physical and mental health of each person, his long years of life, provision of medical care in case of loss of health;

      37) health care system - a set of government and healthcare bodies, ensuring the citizens’ rights for health protection;

      38) medical expertise in healthcare area (hereinafter - the expertise in healthcare) - a set of organizational, analytical and practical measures, aimed at defining the level and quality of tools, techniques, technologies, and services in various healthcare areas;

      39) a standard for healthcare (hereinafter - the standard) – a legal act, defining the rules, common principles and characteristics in medical and pharmaceutical activity, medical and pharmaceutical education;

      40) standardization in healthcare (hereinafter - the standardization) – the activity, aimed at achieving the optimal level of regulation of processes, medical technologies and services via development, introduction and compliance with standards, requirements, rules, instructions and regulations;

      41) an authorized body in healthcare area (hereinafter - the authorized body) - the state body, managing protection of public health, medical and pharmaceutical sciences, medical and pharmaceutical education, healthcare and epidemiological safety, circulation of medicinal products, medical devices and medical equipment, quality control of medical services;

      42) National healthcare holding - the joint stock company, incorporated under the decision of the Government of the Republic of Kazakhstan, working in healthcare area, including nuclear medicine;

      43) a healthcare organization - a legal entity, working in healthcare area;

      43-1) detoxification - a complex of medical measures, aimed at elimination of alcohol from a human body;

      44) diagnostics - a complex of medical services, aimed at detection of presence or absence of a disease;

      45) diagnostic reagents – the reagents, the sets of reagents, designed to study the samples taken from a human body and to provide information about their condition in order to diagnose or evaluate physiological state of a patient;

      46) dynamic observation – a systematic monitoring of the population’s health, as well as providing of necessary medical assistance upon the results of this observation;

      47) a donor - a person, a dead body, an animal, from whom the donor blood and its components, a donor material (including sperm, gametes, eggs) as well as tissues and (or) organs (parts of organs) are taken for transplantation to the recipient;

      48) treatment - a complex of medical services, aimed at elimination, slowing down and (or) relief of disease, and prevention of its progression;

      49) voluntary treatment – the treatment, carried out with the consent of a patient or his legal representative;

      50) adulterated drug – a drug that does not match the composition, properties and other characteristics of the original or generic drugs of producers, which is provided with counterfeit labels unlawfully and knowingly;

      51) a personal medical card – a personal document, issued to the representative of the population’s decreed group, where the results of obligatory medical examinations are recorded with a note of admission to the work;

      52) an acquired immunodeficiency syndrome (AIDS) - the final phase of HIV infection with pathological manifestations, caused by deep immune system impairment of a person with HIV;

      53) invasive methods – the methods of diagnosis and treatment, conducted via penetration into the internal environment of the human body;

      54) innovative medical technologies - a set of methods and tools for scientific and technological activities, introduction of which in medicine (biomedicine), pharmacy and informatization in healthcare is cost-effective and (or) socially important;

      55) infectious and parasitic diseases – human diseases, occurrence and spreading of which is caused by biological environment factors and possibility of transmission of the disease from an infected person or an animal to a healthy person;

      56) iodine deficiency disorders - the pathological process of the body, caused by thyroid gland dysfunction, related to insufficient intake and assimilation of iodine in the body;

      57) an occupational disease – a chronic or acute disease, caused by harmful production factors when performing labor (official) duties;

      58) pre-clinical (non-clinical) research - chemical, physical, biological, microbiological, pharmacological, toxicological and other experimental scientific researches or a series of studies of a test substance or physical impact, devices, methods and technologies for prevention, diagnosis and treatment of diseases in order to study specific action and (or) safety for human health;

      59) a clinical research – a research with participation of a man as a subject, conducted to elucidate or confirm the safety and efficiency of tools, techniques and technologies for prevention, diagnosis and treatment;

      60) council of physicians – examination of a person to make a diagnosis, determine a treatment strategy and prognosis, with involvement of no less than three doctors;

      61) contraception - methods and means of preventing unwanted pregnancy;

      62) State Pharmacopoeia of the Republic of Kazakhstan - a set of national standards and provisions, regulating the quality and safety of medicines;

      63) public health - a comprehensive assessment of mental, physical and social welfare of the population, reflecting the society’s efforts on a healthy lifestyle, including healthy food, prevention of diseases and injuries, as well as prevention of effects of harmful environmental factors;

      64) confidential medical examination – an examination, based on doctor-patient confidentiality and patient privacy;

      65) a certificate of a specialist – a standard document, allowing an individual to render medical services in a particular qualification;

      66) compulsory treatment - treatment of a patient, pursuant to a court decision;

      67) health workers – the individuals with professional medical education, providing medical activities;

      68) medical and social rehabilitation - the recovery of health of patients and the disabled with a complex use of medical, social and occupational activities for their involvement into work, family and social life;

      69) medical immunobiological drugs – the drugs for specific prevention, diagnosis and treatment of infectious and immune (including allergic) diseases, diagnosis of other diseases and physiological states by immunological methods, indication of infectious agents and their antigens in environmental objects, blood products (regardless of production methods), providing curative and preventive effect through the immune system;

      70) medical assistance – a set of comprehensive medical services, including medicinal assistance, aimed at preservation and recovery of the population’s health;

      71) quality of medical care - the level of compliance of medical care with the standards, approved by the authorized body and established on the basis of the current level of medical science and technology development;

      72) medical examination - examination of an individual to establish or confirm the existence or absence of a disease, determine the health state, as well as temporary disability, vocational and other workability;

      73) medical activities - professional activities of individuals with higher or secondary vocational medical education, as well as legal entities, aimed at protecting the citizens’ health;

      74) medical services – healthcare subjects’ actions with prophylactic, diagnostic, therapeutic or rehabilitative purposes for a particular person;

      75) medical devices – the items and materials, used for preventive, diagnostic and therapeutic actions: medical instruments, dental supplies, expendables, dressings and sutures, appliances and medical optics items;

      76) medical rehabilitation - a set of medical services, aimed at reservation, partial or complete recovery of impaired and (or) lost body functions of patients and the disabled;

      77) medical optics products – the items and materials, used in medical and pharmaceutical activity for vision correction and light therapy;

      78) medical equipment - apparatus, instruments and tolls, used separately, in sets or systems in medical purposes to prevent, diagnose, treat and cure diseases, for rehabilitation and medical research;

      79) healthcare organization – a healthcare organization, providing medical care;

      80) a state healthcare and epidemiological supervision - the healthcare-epidemiological service on prevention, detection and suppression of violations of legislature of the Republic of Kazakhstan on healthcare and epidemiological welfare of the population, as well as monitoring of compliance with the regulations in healthcare and epidemiological safety and health standards in order to protect public health, the environment and safety of products, processes and services;

      81) nicotine - an alkaloid, contained in tobacco leaves and tobacco smoke;

      82) nutraceuticals - nutritional supplements, composed of various combinations of specified essential (essential) food ingredients (some amino acids, vitamins, minerals and trace elements, fatty acids, disaccharides, and dietary fiber), that do not exceed the recommended daily requirement;

      83) orphan drugs – the drugs for treatment and diagnosis of orphan (rare) diseases;

      84) orphan (rare) disease - rare serious diseases, threatening human life or resulting in permanent disability, the frequency of which does not exceed an official level;

      85) parapharmacy - biologically active substances of natural origin or their synthetic analogues in therapeutic doses with pharmacological activity, aimed at disease prevention, supportive therapy and regulation of functional activity of organs and systems;

      86) patented drugs - the medicines that have received legal protection in accordance with the legislature of the Republic of Kazakhstan in intellectual property area;

      87) a patient – an individual, who is (was) the consumer of health services;

      88) prevention – a set of comprehensive medical and non-medical actions, aimed at prevention of disease, progression of the early stages of disease and monitoring of the already developed complications, damage of organs and tissues;

      89) psycho-active substances - the substances of synthetic or natural origin, the one-time intake of which influences the mental and physical functions, behavior of a person, and during a long-lasting use they cause mental and physical abuse;

      90) mental disorders (diseases) - a disorder of human mental activity caused by disturbance of brain functions;

      91) a recipient – a patient, who receives donor blood or its components and (or) drugs, a male or female donor material (sperm or egg) or who undergoes transplantation of tissues and (or) an organ (a part of organ) from a donor;

      92) healthcare and quarantine control – a supervision over the healthcare-epidemiological status of the goods and people’s health when transporting people and goods across the state border of the Republic of Kazakhstan, coinciding with the customs border of the Customs Union, carried out in order to prevent import of infectious and parasitic diseases, substances and products, potentially hazardous to human health;

      93) healthcare protection zone - an area, separating the areas of ??special purpose, as well as industrial organizations and other industrial, utility and storage facilities in a human settlement from the surrounding residential areas, civil buildings and houses in order to mitigate influence of adverse factors;

      94) healthcare-epidemiological situation - the status of public health and environment in a particular area at a particular time;

      95) healthcare-epidemiological (preventive) measures – the measures aimed at eliminating or mitigating of harmful effects of environment factors on human health, prevention of emergence and spread of infectious and parasitic diseases, mass poisonings and their elimination;

      95-1) sports medicine - a branch of medicine and healthcare, responsible for biomedical support of athletes, which includes medical and functional control in sports, functional and medical rehabilitation of athletes, improvement of their athletic performance, treatment of their systemic diseases, sports traumatology, emergency assistance in sport and sport's hygiene;

      95-2) a bone marrow – a central organ of hematosis, located in a cancellous bone and medullary canals;

      96) enrichment (fortification) of food - introduction of vitamins, minerals and other substances in food products during their production or processing in order to increase nutritional and biological value, and to prevent diseases, caused by their deficiency;

      97) risk assessment - scientific assessment of likelihood of penetration and spread of pathogens or carriers of infectious and parasitic diseases, as well as the negative impact of environmental factors on human health and the related potential medical-biological and economic consequences;

      98) an independent expert – an individual, accredited in the prescribed manner to conduct an independent expertise of healthcare subjects’ activity;

      99) guaranteed volume of free medical care – a single volume (the list of health care services) of medical assistance, provided for the residents of the Republic of Kazakhstan and the repatriates, and defined by the Government of the Republic of Kazakhstan;

      100) tobacco – a nicotine-containing plant used for tobacco production;

      101) tobacco product - any product containing tobacco, except for pharmaceutical products, containing nicotine;

      102) an ingredient of tobacco product - any substance, except for tobacco, water or tobacco leaf, which is added to tobacco or to non-tobacco ingredients of tobacco products during the manufacturing;

      103) tobacco product packaging - a unit of a consumer packaging, containing a certain number of packs of tobacco products;

      104) a tobacco pack - a unit of consumer packaging, made of cardboard or paper or other material, containing a certain amount of tobacco products;

      105) tobacco smoking - a process of consumption of tobacco products, causing nicotine addiction of a smoker, adversely affecting his and non-smokers’ health and polluting the environment;

      106) transplantation – a transplant, grafting of tissues and (or) organs (parts of organs) to another place in a body or to another body;

      107) a contagious form of TB - the disease, potentially dangerous to other people in the community in connection with TB bacteria discharge by a TB patient into the environment;

      107-1) terminable adaptation - a process of a person’s detoxication from alcohol and his adaptation to the environment;

      108) poisoning - a disease (condition) that arises after acute (one-time) or chronic (long-term) impact of chemical, biological and other environmental factors on a person;

      109) reproductive health – the human health, reflecting the ability to reproduce a full-fledged generation;

      110) pharmacological product - a substance or a mixture of substances with the established pharmacological activity and toxicity, that are clinically tested and a potential drug;

      111) pharmaceutical workers - the individuals with pharmaceutical education, carrying out pharmaceutical activities;

      112) pharmaceutical activity – the activity, carried out in healthcare area for production, manufacturing (except for medical equipment), wholesale and retail selling of medicines, medical supplies and medical equipment, which is related to procurement (acquisition), storage, import, export, quality control, design, distribution, use and disposal of medicines, medical devices and medical equipment, as well as their safety, efficiency and quality;

      113) the products, potentially dangerous to public health – the products, defined by the authorized body, that can have harmful effects on human health during their application or use;

      114) healthcare-epidemiological welfare of the population - the health status of the population, when there are no harmful environmental factors, affecting human health and favorable conditions for life shall be provided;

      115) activity in healthcare and epidemiological welfare of the population - the activity of the state bodies and healthcare -epidemiological service organizations, aimed at protection of people’s health, including the state healthcare and epidemiological supervision, hygienic education, healthcare-quarantine control, radiation monitoring, healthcare-epidemiological valuation, risk assessment, healthcare and epidemiological monitoring, healthcare-epidemiological expertise;

      116) surgical sterilization - a surgical operation, in the result of which a man or a woman loses fertility;

      117) live births and stillbirths of a fetus - a state of a newborn baby (fetus), assessed by the relevant international standards of the World Health Organization on live births and stillbirths of a fetus;

      118) restrictive measures, including quarantine – the measures, aimed at prevention of infectious diseases’ spread and providing for a special mode of business and (or) other activities;

      119) euthanasia - satisfaction of a terminally ill person’s request on quickening of his death by any actions, including injection of drugs or other means, as well as cessation of artificial measures to maintain his life in the cases of an adverse outcome of a disease;

      120) epidemic – a mass spreading of infectious diseases, which is significantly higher than the usual registered incidence;

      121) epidemiologically valued objects – the objects, the products and (or) activity of which can lead to food poisoning and breakouts of infectious diseases in the population if the requirements of the legislation of the Republic of Kazakhstan on healthcare and epidemiological welfare of the population shall be violated;

      122) nuclear medicine – the branch of a medicine, focused on prevention, diagnosis and treatment of various diseases of human organs and systems, including cancer diseases, where radioactive elements and ionizing radiation shall be applied.

      2. The content of other terms shall be defined by certain articles of this Code.

      Footnote. Article 1, as amended by the Laws of the Republic of Kazakhstan dated on 30.06.2010 No 297-IV (shall be enforced from 01.07.2011); dated on 29.12.2010 No 372-IV (shall be enforced upon expiration often calendar days after its first official publication); dated on 19.01.2011 No 395-IV (shall be enforced upon expiration often calendar days after its first official publication); dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011); dated on 27.04.2012 No 15-V (shall be enforced upon expiration often calendar days after its first official publication); dated on 10.07.2012 No 31-V (shall be enforced upon expiration often calendar days after its first official publication).

**Article 2. The scope of this Code**

      1. This Code regulates public relations in healthcare area in order to implement the citizens’ constitutional right to health protection.

      2. The legal relationships, defined by the legislature of the Republic of Kazakhstan in healthcare, in terms of selecting a service provider for the guaranteed free medical care volume and reimbursement of expenditures to the healthcare organizations, as well as procurement of medicines and medical devices in the frames of the guaranteed free medical care volume, shall not be covered by the legislation of the Republic of Kazakhstan on public procurement.

      Footnote. Article 2, as amended by the Law of the Republic of Kazakhstan, dated on 28.06.2012 No 22-V (shall be enforced from 07.01.2012).

**Article 3. Legislation of the Republic of Kazakhstan in healthcare area**

      1. Legislation of the Republic of Kazakhstan in healthcare area is based on the Constitution of the Republic of Kazakhstan and consists of this Code and other regulatory legal acts of the Republic of Kazakhstan.

      2. If an international treaty, ratified by the Republic of Kazakhstan, establishes the rules other than those contained in the Code, the rules of the international treaty shall be applied.

 **Chapter 2. THE STATE REGULATION AND MANAGEMENT IN HEALTHCARE AREA**

**Article 4. Principles of the State Policy in healthcare area**

      The state healthcare policy shall be based on the following principles:

      1) equal rights of citizens for safe, effective and qualitative medical care;

      2) a joint responsibility of the state, employers and individuals for preservation and strengthening of individual and public health;

      3) maternal and child health;

      4) a guaranteed volume of free medical care;

      5) priority of preventive directions in healthcare system;

      6) accessibility of medical care;

      7) regular improvement of medical care quality;

      8) healthcare and epidemiological welfare of the population;

      9) continuity of the healthcare organizations’ activity in rendering medical assistance;

      10) continuity of medical and pharmaceutical education, using modern teaching technologies;

      11) the state support for domestic medical science, introduction of advanced scientific developments, technology and international experience in healthcare;

      12) encouragement of voluntary unpaid donorship;

      13) the state support of local development and expansion of competitive medical and pharmaceutical industries;

      14) involvement of social organizations in ensuring the citizens’ rights for health protection;

      15) social orientation of healthcare system to meet the needs of the population and improve the quality of life;

      16) promotion of a healthy lifestyle and healthy eating;

      17) assignment of public health, safety, efficacy and quality of drugs to the factors of national security.

**Article 5. Principles of the state regulation in healthcare area**

      1. The state healthcare regulation shall be performed by:

      1) the President of the Republic of Kazakhstan;

      2) the Government of the Republic of Kazakhstan;

      3) the authorized body;

      4) other central and local executive bodies within their competence, defined by this Code and other Laws of the Republic of Kazakhstan, decrees of the President of the Republic of Kazakhstan and the Government of the Republic of Kazakhstan.

      2. The state regulation of healthcare shall be conducted by:

      1) the state control over the medical and pharmaceutical activity and the state healthcare and epidemiological supervision;

      2) the licensing of medical and pharmaceutical activity;

      3) accreditation in healthcare area;

      4) certification in healthcare area;

      5) the state registration, re-registration and amendments to the registration dossier of medicinal products, medical devices and medical equipment, certain types of products and substances that have harmful effects on human health;

      6) confirmation of goods’ (works’, services’) compliance with the healthcare requirements, defined by the technical regulations, regulatory standardization documents and contracts, except for the drugs, medical supplies and medical equipment;

      7) the state regulation of prices for medicines and medical services, provided by the state health organizations.

      Footnote. Article 5 as amended by the Laws of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011); dated on 10.07.2012 No 34-V (shall be enforced from the date of its first official publication); dated on 21.06.2013 No 107-V (shall be enforced upon expiration of thirty calendar days after its first official publication).

**Article 6. Competence of the Government of the Republic of Kazakhstan**

      The Government of the Republic of Kazakhstan shall:

      1) develop the main directions of the state healthcare policy;

      2) elaborate the normative legal acts in healthcare, healthcare rules, hygienic standards within its competence;

      3) approve the state control procedure for healthcare;

      4) define the procedure for accreditation in healthcare area;

      5) approve qualification requirements for medical and pharmaceutical activity;

      6) manage the central and local authorities on healthcare issues;

      7) approve the list of the guaranteed volume of free medical care;

      8) define the procedure for providing the guaranteed volume of free medical care;

      9) specify the order, type and the amount of medical care in emergency situations;

      10) approve a standard contract form for a guaranteed volume of free medical care and the paid services in health care organizations;

      11) approve the state standard for healthcare organizations’ network;

      12) define the procurement procedure of drugs, medical supplies and medical equipment, medical and pharmaceutical services to provide the guaranteed free medical care;

      12-1) approve the rules of assessment of the safety and quality of medicines and medical devices, registered in the Republic of Kazakhstan;

      13) establish the list of socially significant diseases, posing danger to others;

      14) specify the rules for sending Kazakhstan citizens abroad for medical treatment at the expense of budget funds;

      15) define the order of reimbursement of healthcare organizations’ expenditures from the budget;

      16) determine the procedure for healthcare-quarantine control over bringing in and spreading of infectious and parasitic diseases at the state border of the Republic of Kazakhstan, coinciding with the customs border of the Customs Union, and healthcare protection of the border and territory of the Republic of Kazakhstan;

      17) define the order for banning importation, as well as production, use and selling of products in the Republic of Kazakhstan, designed for public use, as well as business and (or) other activities;

      18) specify the list of diseases against which vaccinations are carried out, the order, time-frames and groups subject to routine immunization;

      19) establish the procedure of restrictive measures, including quarantine in the Republic of Kazakhstan, as well as the special conditions and modes of living and doing business and (or) other activities;

      20) establish a list of communicable diseases, when restrictive measures, including quarantine shall be introduced to prevent their emergence and spread;

      21) establish the procedure for sampling, storage and use of blood and tissues of persons, exposed to ionizing radiation;

      22) define a procedure for providing medicines to citizens;

      23) define the cases for import of medicines, medical supplies and medical equipment as a humanitarian aid into the Republic of Kazakhstan that have not been officially registered in the Republic of Kazakhstan;

      24) approve the list of clinical sites;

      25) approve the procedure and conditions for transferring an anatomical gift to healthcare organizations;

      26) approve the Rules of military medical expertise and Regulations on military medical examination bodies;

      27) define a single distributor for purchasing and providing drugs, medical products;

      27-1) approve the concept for nuclear medicine development in the Republic of Kazakhstan;

      27-2) approve the procedure for health care provision;

      28) perform other functions, assigned to it by the Constitution, the laws of the Republic of Kazakhstan and the acts of the President of the Republic of Kazakhstan.

      Footnote. Article 6 as amended by the Laws of the Republic of Kazakhstan, dated on 30.06.2010 No 297-IV (shall be enforced from 01.07.2011); dated on 19.01.2011 No 395-IV (shall be enforced upon expiration often calendar days after its first official publication); dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011); dated on 15.07.2011 No 461-IV (shall be enforced from 30.01.2012); dated on 10.07.2012 No 34-V (shall be enforced from the day of its first official publication).

**Article 7. The competence of the authorized body**

      1. The authorized body shall:

      1) implement the state policy in healthcare;

      2) develop the state planning system in healthcare;

      3) prioritize scientific developments in healthcare;

      4)

excluded by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011);

      5) develop and approve the regulations and forms of records and reports related to healthcare within its competence;

      6) elaborate and adopt standards;

      7) carry out the monitoring in the healthcare area;

      7-1) coordinate and provide the methodical management of local executive bodies in the field of health care;

      8) coordinate the healthcare subjects’ activities;

      9) provide departmental statistical surveillance in public health area;

      10) create and provide functioning of electronic information resources and information systems, information and communication networks in healthcare, their accessibility for individuals and legal entities in accordance with the legislature of the Republic of Kazakhstan on information;

      11) develop and adopt a branch encouragement system and the order of awarding honorary titles in healthcare;

      12) develop medical and pharmaceutical science and coordinates research activities in healthcare;

      13)

excluded by the Law of the Republic of Kazakhstan, dated on 13.01.2014 No 159-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      14) introduce new methods of prevention, diagnosis, treatment and rehabilitation, as well as control them;

      15) place a state education order for training at medical and pharmaceutical majors, as well as improvement of skills and retraining of medical and pharmaceutical personnel in healthcare;

      16) agree the appointment of heads of local state bodies for healthcare management;

      17) sign memorandum with the heads of local executive bodies, focused on the achievement of final results of activity in healthcare area;

      18)

excluded by the Law of the Republic of Kazakhstan, dated on 13.01.2014 No 159-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      19)

excluded by the Law of the Republic of Kazakhstan, dated on 13.01.2014 No 159-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      20) carry out the state regulation of prices for medicines and medical services rendered by public healthcare organizations;

      21) carry out outputs on equipping of public healthcare organizations;

      22) choose a service provider for a guaranteed volume of free medical care under the administered budget programs and reimbursement of its costs;

      23)

excluded by the Law of the Republic of Kazakhstan, dated on 13.01.2014 No 159-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      24) organize and carry out the state certification of scientific organizations and educational organizations in healthcare area;

      25) carry out attestations of professional competence of the leaders of local healthcare state bodies, national healthcare organizations and their deputies, and specify the order of certification in healthcare area;

      26) organize accreditation of healthcare subjects;

      27) accredit individuals to carry out an independent expertise of the healthcare subjects’ activity;

      28) organize the qualifying examinations in healthcare area;

      29)

excluded by the Law of the Republic of Kazakhstan, dated on 13.06.2013 No 102-V (shall be enforced upon expiration of ten calendar days after its first official publication).

      29-1) develop the rules for safety and quality assessment of medicines and medical devices, registered in the Republic of Kazakhstan;

      29-2) approve the order of formation of the registry of healthcare subjects, providing wholesale and retail selling of medical devices and medical equipment in the notification procedure;

      29-3) keep a register of healthcare subjects, engaged in wholesale distribution of medical devices and medical equipment;

      29-4) license the entry to the territory of the Republic of Kazakhstan from countries, non-aligned to the Customs Union, and export of organs (parts of organs) and (or) human tissues, blood and its components from the territory of the Republic of Kazakhstan to these countries;

      29-5) define the order of determination (consent documents) for the entry to the territory of the Republic of Kazakhstan and export of hepoietic stem cells and a bone marrow from the territory of the Republic of Kazakhstan, in case of their migration in order to carry out an unrelated transplantation, as well as samples of cells, tissues, biological fluids and secretions, as well as human waste products, physiologic and pathologic discharges, swabs, scrapes and lavages, dealing with diagnostic purposes or received in the process of carrying out the biomedical testings;

      29-6) conduct the determination (consent documents) for the entry of medicine, health products and medical devices (as well as non-registered) as humanitarian supplies or attendance in emergency to the territory of the Republic of Kazakhstan;

      30) recognize the standards of international and foreign pharmacopoeias and pharmacopoeial articles (monographs) and other normative documents on standardization of medicines, medical supplies and medical devices of foreign countries;

      31) conduct the state registration, re-registration and amends the registration dossier, revokes a decision on the state registration of medicines, medical supplies and medical equipment, keeps the State register of medicines, medical supplies and medical devices;

      32) conform the import of medicines, medical supplies and medical devices to the territory of the Republic of Kazakhstan;

      33) introduce restrictive measures, including quarantine, with the special conditions of economic and (or) other activities and life of the population;

      34) keep the register of potentially dangerous chemical and biological substances, prohibited for use in the Republic of Kazakhstan;

      35) coordinate the projects of national and international standards for products, goods, processes, services, and design standards within its competence;

      36) conduct the state registration of baby food, nutritious and dietary supplements, genetically modified organisms, materials and articles, contacting with water and food, disinfection, disinfestation and deratization equipment, certain types of products and substances that have harmful effects on human health;

      37)

excluded by the Law of the Republic of Kazakhstan, dated on 03.07.2013 No 124-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      38) implement joint international projects in healthcare;

      39)

excluded by the Law of the Republic of Kazakhstan, dated on 13.01.2014 No 159-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      40) define the level of citizens' satisfaction with the quality of medical assistance;

      41) consider applications of individuals and legal entities on healthcare issues;

      42) organize hygiene education, promotes healthy lifestyles and healthy eating;

      43)

excluded by the Law of the Republic of Kazakhstan, dated on 13.01.2014 No 159-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      44) organize and implement anti-epidemic (preventive) measures in case of food poisoning, infectious and other diseases within its jurisdiction;

      45) issue healthcare-epidemiological conclusions on compliance (non-compliance) of the State Healthcare and Epidemiological Surveillance object with the normative legal acts on healthcare and epidemiological safety and health standards;

      46)

excluded by the Law of the Republic of Kazakhstan, dated on 13.01.2014 No 159-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      47) conduct public control over the healthcare subjects’ activity;

      48)

excluded by the Law of the Republic of Kazakhstan, dated on 13.01.2014 No 159-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      49) conduct the state control over observance of the standards and legislature of the Republic of Kazakhstan on licensing for medical and pharmaceutical activities;

      50) perform the state control in circulation of drugs, medical supplies and medical equipment, as well as trafficking of drugs, psychotropic substances and precursors in healthcare area;

      50-1) perform the state control over evaluation of safety and quality of medicines and medical devices, registered in the Republic of Kazakhstan;

      51) implement epidemiological surveillance of infectious diseases;

      52) control examinations in healthcare;

      53) control advertising of medical services, drugs, medical supplies and medical equipment, dietary supplements, as well as methods of prevention, diagnosis, treatment and medical rehabilitation;

      54) consider cases on administrative offenses and imposes administrative penalties in accordance with the legislature of the Republic of Kazakhstan on administrative offences;

      55) conduct the state healthcare and epidemiological surveillance in the Republic of Kazakhstan;

      56) control organization of vaccinations of the population;

      57) conduct the state healthcare-epidemiological examination of projects;

      58) define the territory or part of it, free of disease or with a low level of diseases incidence;

      59)

excluded by the Law of the Republic of Kazakhstan, dated on 13.01.2014 No 159-V (shall be enforced upon expiration of ten calendar days after its first official publication); 60) create healthcare and quarantine stations at the border checkpoints of the state border of the Republic of Kazakhstan, coinciding with the customs border of the Customs Union;

      61) approve the list of epidemiologically significant facilities;

      62)

excluded by the Law of the Republic of Kazakhstan, dated on 10.07.2012 No 36-V (shall be enforced upon expiration often calendar days after its first official publication);

      63) define a common methodology for all organizations eligible to conduct risk assessment, and establishes the order of risk assessment;

      64)

excluded by the Law of the Republic of Kazakhstan, dated on 13.01.2014 No 159-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      65) develop and approve the State Pharmacopoeia of the Republic of Kazakhstan;

      66) conduct international cooperation in the healthcare area, including medical and pharmaceutical science, medical and pharmaceutical education;

      67) control rational prescribing, as well as the effective use of medical equipment in public health organizations;

      68) define the List of medicines, medical supplies, purchased from a single distributor for procurement and supply of drugs, medical products;

      69)

excluded by the Law of the Republic of Kazakhstan, dated on 13.01.2014 No 159-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      70) approve the procedures for development and coordination of medicinal forms in health care organizations;

      71) adopt the rules of inspection in circulation of drugs, medical supplies and medical equipment;

      72) elaborate and approve the forms of mandatory departmental accountability, checklists, risk assessment criteria, semiannual audit plans in accordance with the Law of the Republic of Kazakhstan "On State Control and Supervision in the Republic of Kazakhstan";

      73) approve the procedure for medical examinations of persons applying for a driving license.

      2. The authorized body shall perform other functions, provided by this Code, other laws, acts of the President of the Republic of Kazakhstan and the Government of the Republic of Kazakhstan.

      Footnote. Article 7 as amended by the Laws of the Republic of Kazakhstan, dated on 30.06.2010 No 297-IV (shall be enforced from 01.07.2011); dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011); dated on 15.07.2011 No 461 -IV (shall be enforced from 30.01.2012); dated on 28.06.2012 No 22-V (shall be enforced from 01.07.2012); dated on 10.07.2012 No 31-V (shall be enforced upon expiration often calendar days after its first official publication); dated on 10.07.2012 No 34-V (shall be enforced from the date of its first official publication); dated on 10.07.2012 No 36-V (shall be enforced upon expiration often calendar days after its first official publication); dated on 08.01.2013 No 64-V (shall be enforced from 01.01.2013), dated on 13.06.2013 No 102-V (shall be enforced upon expiration of ten calendar days after its first official publication); dated on 21.06.2013 No 107-V (shall be enforced upon expiration of thirty calendar days after its first official publication); dated on 03.07.2013 No 124-V (shall be enforced upon expiration of ten calendar days after its first official publication); dated on 13.01.2014 No 159-V (shall be enforced upon expiration of ten calendar days after its first official publication).

**Article 8. Competence of central executive bodies and other central state agencies with military-medical (medical) subdivisions**

      The central executive bodies and other central government agencies that have military-medical (medical) subdivisions within their competence,shall:

      1) implement the state healthcare policy;

      2) manage the work of military-medical (medical) subdivisions;

      3) approve the order of military-medical (medical) support to the military-medical (medical) subdivisions;

      4) appoint and dismiss heads of military-medical (medical) subdivisions;

      5) ensure establishment and operation of electronic information resources and information systems, information and communication networks in healthcare;

      6) approve the procedure for medical assistance in military-medical (medical) subdivisions;

      7) develop and adopt the structure of organizations and departments, the regulations for their activities, the model personnel and personnel regulations in military-medical (medical) subdivisions;

      8)

excluded by the Law of the Republic of Kazakhstan, dated on 03.07.2013 No 124-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      9) make proposals to the authorized body on introduction (cancellation) of restrictive measures, including quarantine, in the military-medical (medical) subdivisions;

      10) define the order and frequency of medical examinations of the relevant contingent in military-medical (medical) subdivisions;

      11) approve the structure and the Regulation on military-medical commission.

      Footnote. Article 8 as amended by the Law of the Republic of Kazakhstan, dated on 03.07.2013 No 124-V (shall be enforced upon expiration of yen calendar days after its first official publication).

**Article 9. Competence of local self-government bodies of regions, town of republican importance and the capital**

      1. Local representative bodies of regions, a city of republican significance and the capital shall:

      1)

excluded by the Law of the Republic of Kazakhstan, dated on 03.07.2013 No 124-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      2) define a system of social support measures for medical and pharmaceutical workers, sent to work in the countryside, as well as the procedure and amount of social support to them at the expense of budget funds;

      3) approve local budgets of healthcare and medical education and reports on their implementation;

      4) take a decision to provide free or reduced travel fee to the citizens, going outside a village for medical treatment at the expense of budget funds;

      5) take a decision on additional supply of pharmaceuticals, the specialized medical products, medical supplies for free and on preferential terms for certain categories of individuals in outpatient treatment;

      6) approve measures, aimed at development and operation of healthcare organizations;

      7) take a decision to provide additional encouragement for donors;

      8) take a decision on additional personnel and logistics supply for public healthcare organizations, if the minimal standards, approved by the authorized body, have been implemented in full;

      9) promote a healthy lifestyle and healthy eating;

      10) exercise other powers to ensure the rights and legitimate interest of citizens in accordance with legislation of the Republic of Kazakhstan.

      2. Local executive bodies of regions, a city of republican status and the capital shall:

      1) implement the state healthcare policy at the relevant administrative-territorial unit;

      2)

excluded by the Law of the Republic of Kazakhstan, dated on 03.07.2013 No 124-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      3) implement the citizens’ right to a guaranteed volume of free medical care, including medical services for temporary adaptation and detoxification;

      4) implement measures to promote voluntary unpaid donation of blood and its components;

      5) create local healthcare government agencies;

      6) organize control over staffing of public healthcare organizations;

      7) take measures to develop healthcare organizations’ network and their financial and logistical support, including development of the state pharmacies network and establishment of pharmaceutical warehouses;

      8) coordinate the activities of public and private healthcare sectors;

      9) provide free medical care, medicines and medical supplies in emergency situations;

      10) conduct inter-regional and international cooperation in healthcare area;

      11) conduct licensing in accordance with the legislature of the Republic of Kazakhstan on licensing;

      12) provide training, professional development and retraining of medical and pharmaceutical personnel;

      13) conduct the measures needed to improve health, prevent diseases, promote healthy lifestyles and healthy eating;

      14) provide specialized medical assistance to the population, including prevention and treatment of socially significant diseases and the diseases that are dangerous to others, including drugs supply within the frames of the guaranteed volume of free medical care in accordance with the established national standards;

      15) send children with disabilities to psychological, medical and pedagogical counseling with the consent of parents or other legal representatives,;

      16) exercise the state control in healthcare area within their competence;

      17) conclude and implement a memorandum with the authorized body to progress in healthcare area;

      18) support fulfillment of a court decision on sending a citizen with infectious tuberculosis for compulsory medical treatment;

      18-1) keep a register of subjects, engaged in retail selling of medical supplies and medical equipment;

      18-2) keep a register of subjects, carrying out a retail of health products and health devices;

      19) exercise other powers, delegated to local executive bodies by the legislation of the Republic of Kazakhstan in the interests of the local state management.

      Footnote. Article 9 as amended by the Laws of the Republic of Kazakhstan dated on 29.12.2010 No 372-IV (shall be enforced upon expiration often calendar days after its first official publication); dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011); dated on 10.07.2012 No 31-V (shall be enforced upon expiration often calendar days after its first official publication); dated on 10.07.2012 No 36-V (shall be enforced upon expiration often calendar days after its first official publication); dated on 13.06.2013 No 102-V (shall be enforced upon expiration of ten calendar days after its first official publication), by the Constitution Law of the Republic of Kazakhstan, dated on 03.07.2013 No 121-V ( shall be enforced upon expiration of ten calendar days after its first official publication).

**Article 10. Competence of local state healthcare bodies of regions, a city of republican status and the capital**

      Within their powers the local state healthcare bodies of regions, a city of republican status and the capital:

      1) implement the state healthcare policy and ensure implementation of regional healthcare programs;

      2) ensure fulfillment of the legislature of the Republic of Kazakhstan in healthcare area, education and science;

      3) provide citizens and repatriates with medical assistance and pharmaceutical products, medical supplies within the frames of the guaranteed volume of free medical care, including medical services for temporary adaptation and detoxification;

      4) organize, monitor and control the activities of healthcare subjects;

      5) conduct functions of administers of budgetary healthcare programs;

      6) select a provider of medical and pharmaceutical services for the guaranteed volume of free medical care and reimbursement of its expenses;

      7) procure medicines, preventive (immunobiological, diagnostic, disinfecting) drugs in the frames of the guaranteed volume of free medical care in accordance with the procedure established by the Government of the Republic of Kazakhstan:

      on an outpatient basis – in compliance with the list, approved by the authorized body;

      on an inpatient basis - within the pharmaceutical forms;

      8) procure medical supplies and medical equipment, non-medical equipment, ambulances, as well as the services for overhaul reparations of public healthcare organizations;

      9) organize the human resourcing of public healthcare organizations;

      10) provide equipping of public healthcare organizations;

      11) provide creation and functioning of regional electronic information resources and information systems, information and communication networks in healthcare area;

      12) provide clinical facilities in public healthcare organizations, financed by the local budget, for higher and secondary medical schools;

      13) provide free medical care, medicines and medical supplies in emergency situations;

      14) organize and coordinate training, professional development and retraining of medical and pharmaceutical personnel;

      15) organize hygienic education, promotion and development of healthy lifestyles and healthy eating;

      16) inform the population about the prevalence rate of socially significant diseases that are dangerous to others;

      17) cooperate with international and non-governmental public organizations concerning the protection of public health;

      18) conduct institutional statistical surveys in healthcare within the relevant administrative-territorial unit in compliance with the statistical methodology requirements;

      19) conduct certification of professional competence of the leaders of subordinate state healthcare organizations.

      Footnote. Article 10 as amended by the Laws of the Republic of Kazakhstan, dated on 19.03.2010 No 258-IV; dated on 29.12.2010 No 372-IV (shall be enforced upon expiration often calendar days after its first official publication); dated on 28.06.2012 No 22-V (shall be enforced from 01.07.2012.); dated on 03.07.2013 No 124-V (shall be enforced upon expiration of ten calendar days after its first official publication).

**Article 11. Functions of the National Healthcare Holding**

      1. The functions of the National Healthcare Holding shall be:

      1) participation in implementation of public healthcare policy;

      2)

excluded by the Law of the Republic of Kazakhstan, dated on 03.07.2013 No 124-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      3) provision of all types of medical assistance;

      4) testing, introduction and transfer of innovative medical technologies to healthcare and education organizations of the Republic of Kazakhstan;

      5) participation in organization of pre-clinical (non-clinical) and clinical researches of drugs, medical devices and medical equipment;

      6) participation in the development and implementation of standards in healthcare organizations;

      7) provision of consulting, informative, electronic and other services;

      8) international cooperation in healthcare area;

      9) participation in healthcare projects;

      10) carrying out other functions provided by the constituent documents.

      2. The National Healthcare Holding may request and receive information from the state bodies in compliance with the requirements, established by the legislative acts of the Republic Kazakhstan on disclosure of information, containing commercial and other secrets, protected by the law in order to conduct the entrusted functions..

      Footnote. Article 11 as amended by the Law of the Republic of Kazakhstan, dated on 03.07.2013 No 124-V (shall be enforced upon expiration of ten calendar days after its first official publication).

**Article 12. Inter-departmental cooperation in healthcare area**

      1. In order to implement the state policy in healthcare, the state bodies and organizations within their competence must support the state bodies, regulating the healthcare area.

      2. In order to provide interaction between the state bodies, international and other healthcare organizations, a national coordinating healthcare authority is established under the Government of the Republic of Kazakhstan, the status and powers of which are defined by the Government of the Republic of Kazakhstan. Regional coordinating healthcare bodies shall be established in local executive bodies, the status and powers of which shall be defined by the local executive authorities.

      3. Coordination and cooperation between the government agencies and healthcare organizations in emergency medicine shall be performed by the authorized body for natural and man-made disasters.

      4. Normative legal acts and regulations that are directly or indirectly related to the public health and healthcare system, developed by the central executive bodies shall be be coordinated with the authorized body.

      5. Normative legal acts in healthcare area shall be subject to compulsory implementation by the authorities and organizations, regardless of their departmental affiliation.

      6. Public authorities with departmental medical services shall provide a departmental report on the work of subordinate healthcare organizations (departments) and health status of the attached contingent to the local public authorities for healthcare management.

      7. Heads of departmental healthcare services of the state bodies shall be appointed by the heads of relevant state bodies upon consultation with the authorized body.

      8. Interaction of electronic information resources and information systems, information and communication healthcare networks with the information resources and information systems, information and communication networks of other government agencies for the data exchange shall be performed in accordance with legislation of the Republic of Kazakhstan on informatization.

      9. Public authorities with departmental medical services shall coordinate technical parameters of departmental medical information systems, as well as the content of electronic information resources with the authorized body.

      Footnote. Article 12 as amended by the Law of the Republic of Kazakhstan, dated on 19.03.2010 No 258-IV.

 **Chapter 3. LICENSING, ACCREDITATION AND CERTIFICATION IN HEALTHCARE AREA**

**Article 13. Licensing of medical and pharmaceutical activities, as well as entry, export of organs (organ parts) and (or) Human tissues, blood and its components**

      Medical and pharmaceutical activities shall be subject to licensing in accordance with the legislature of the Republic of Kazakhstan on licensing.

      The entry to the territory of the Republic of Kazakhstan from countries, non-aligned to the Customs union and export of organs (organ parts) and (or) human tissues. Blood and its components, except for the hemopoietic stem cells, bone marrow in case of their migration in order to conduct unrelated transplantation, as well as sample of cells, tissues, biological fluids and secrecy, as well as human waste products, physiologic and pathologic discharges, swabs, scrapes, lavages,dealing with diagnostic and scientific purposes or received in the process of carrying out the biomedical testing shall be conducted subject to permits, iisuedby the authorized body from the territory of the Republic of Kazakhstan to these countries.

      Footnote. Article 13 is in the wording of the Law of the Republic of Kazakhstan, dated on 21.06.2013 No 107-V (shall be enforced upon expiration of thirty calendar days after its first official publication).

**Article 13-1. Notification in healthcare area**

      The following activities in healthcare area shall be performed upon notification:

      1) hygienic training of population;

      2) wholesale trade of medical products;

      3) wholesale trade of medical equipment;

      4) retail trade of medical products;

      5) retail trade of medical equipment.

      Footnote. Chapter 3 shall be supplemented by the Article 13-1 in accordance with the Law of the Republic of Kazakhstan, dated on 10.07.2012 No 36-V (shall be enforced upon expiration often calendar days after its official publication.)

**Article 14. Accreditation in healthcare area**

      1. Accreditation in healthcare area shall be subject to healthcare subjects and the subjects in the scope of circulation of drugs, medical devices and medical equipment in order to recognize the compliance of the medical and pharmaceutical services with the requirements and standards, specified in healthcare area.

      Individuals shall be subject to accreditation to conduct an independent expertise of healthcare subjects’ activity.

      2. Accreditation is voluntary and shall be carried out at the expense of the subject, that is being accredited and other non-prohibited tools.

      3. Accreditation of healthcare subjects shall be based on a comprehensive external evaluation of their activities’ compliance with the established accreditation standards, approved by the authorized body, and shall be taken into account when placing the state order.

      4. Accreditation of individuals for an independent examination of healthcare subjects shall be based on a comprehensive assessment of their qualifications.

      The order of involvement of independent experts shall be established by the Government of the Republic of Kazakhstan.

      5. Accreditation shall be performed by the authorized body or organization, accredited by the authorized body.

      6. The body (organization), implementing (performing) the accreditation of healthcare providers shall create the appropriate accreditation commissions and forms a database of the accredited subjects and independent experts in healthcare area.

      The Charter of the accreditation commission shall be approved by the authorized body.

      Footnote. Article 14 as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 15. Certification in healthcare area**

      1. Certification in healthcare -the periodically performed procedure for defining the level of professional competence of the leaders of local state bodies for healthcare management, the leaders of republican healthcare organizations and their deputies (with medical education), as well as the heads of public healthcare organizations, subordinate to local healthcare state bodies of regions, a town of republican significance and the capital (hereinafter - the persons, who are being certified).

      2. The authorized body certifies the professional competence of the leaders of local state bodies for healthcare management, national healthcare organizations and their deputies (with medical education).

      3. Local state bodies for healthcare management of regions, a city of republican status and the capital (hereinafter - the local healthcare management state bodies) certify the professional competence of the heads of subordinate public healthcare organizations.

      4. The authorized body and local healthcare management state bodies establish certification commissions in order to conduct objective and competent certification.

      5. The main assessment criterion in certification is the competence of the certified individuals in performing their duties.

      6. The certified persons shall be certified upon expiration of every three years, but not earlier than one year from the date of occupying a relevant position.

 **Chapter 4. THE STANDARDS, VERIFICATION OF CONFORMITY OF GOODS (WORKS, SERVICES) AND ADVERTISING IN HEALTHCARE**

**Article 16. Standards in healthcare area**

      1. Types of healthcare standards shall be:

      1) standards for accreditation of healthcare organizations;

      2) standards of operating procedures in healthcare;

      3) standards of medical and pharmaceutical education;

      4) standards for circulation of drugs, medical devices and medical equipment.

      2. Standards in healthcare shall be approved in the order, defined by the legislature of the Republic of Kazakhstan.

**Article 17. Verification of conformity of the goods (works, services) in healthcare area**

      1. Verification of conformity of the goods (works, services) in healthcare, except for the drugs, medical devices and medical equipment shall be conducted in order to assess their safety for human health and life and shall be performed in accordance with legislation of the Republic of Kazakhstan on technical regulation.

      2.

excluded by the Law of the Republic of Kazakhstan, dated on 10.07.2012 No 34-V (shall be enforced from the date of its first official publication).

      3.

excluded by the Law of the Republic of Kazakhstan, dated on 10.07.2012 No 34-V (shall be enforced from the date of its first official publication).

      Footnote. Article 17 as amended by the Law of the Republic of Kazakhstan, dated on 10.07.2012 No 34-V (shall be enforced from the date of its first official publication).

**Article 18. Advertising in healthcare area**

      1. Advertising of drugs, medical devices and medical equipment is performed if a permission is available, issued in the order, established by the authorized body.

      2. Advertising of medical services, methods and tools for prevention, diagnosis, treatment and medical rehabilitation (hereinafter – the services), drugs, medical supplies and medical equipment, dietary supplements must be truthful, recognizable without special knowledge or use of special tools, exclude comparison with other services, drugs, medical supplies and medical equipment, biologically active supplements, and may not mislead consumers by abusing their trust, including in terms of performance, composition, consumer characteristics, cost (price), the expected results after their use, the results of research and testing.

      3. It shall be prohibited:

      1) to advertise drugs, medical devices and medical equipment, dietary supplements and prevention means, that are not registered in the Republic of Kazakhstan;

      2) to distribute the samples of drugs, which are put on doctor's prescription, for advertising purposes;

      3) to involve children, their images and voices in advertising drugs, medical devices, except for the drugs and medical supplies, produced for children;

      4) to distribute and advertise drugs, medical devices and medical equipment, dietary supplements in public transport, in the organizations that shall not be related to their prescription, use and sale;

      5) to place external (visual) advertising of drugs, medical devices and medical equipment, in the form of posters, stands, illuminated panels, billboards, banners, and other stationary advertising objects;

      6) to involve medical professionals, authorized to prescribe drugs and medical devices, as advertisement distributors, unless the cases on distribution of information on drugs and medical devices for scientific or educational purposes, as well as to inform the patients;

      7) to advertise drugs, medical devices and medical equipment if a license for relevant activity and permission for advertising, issued in the order, defined by the authorized body is not available;

      7-1) advertising of services in the absence of a license for relevant activity;

      8) to advertise services rendered by the individuals, who do not have a license for medical activity.

      4. Advertising of drugs, medical devices and medical equipment shall be carried out under the permission of the authorized body, issued after a preliminary examination of the promotional material by the expert body, defined by the authorized body.

      5. Distribution and placement of advertising services, pharmaceuticals, medical devices and medical equipment shall be allowed in specialized medical journals, other media, and healthcare organizations.

      Advertising of prescription medicines, including those containing narcotic drugs, psychotropic substances and precursors, may be conducted only in specialized print media for medical and pharmaceutical workers.

      6. Control over production, distribution and placement of advertising shall be conducted by the authorized body and the state bodies within their competence.

      Footnote. Article 18 as amended by the Law of the Republic of Kazakhstan, dated on 15.07.2011 No 461-IV (shall be enforced 30.01.2012).

 **Chapter 5. THE STATE CONTROL AND SUPERVISION IN HEALTHCARE AREA**

**Article 19. The state control and supervision in healthcare area**

      1. The state control and supervision in healthcare is a complex of measures, aimed at verification of compliance and performance of the requirements of the legislation of the Republic of Kazakhstan, as well as the prevention, suppression and elimination of violations in healthcare area.

      2. The state control and supervision shall be performed in:

      1) provision of medical services;

      2) healthcare and epidemiological welfare of the population;

      3) circulation of drugs, medical devices and medical equipment.

      3. The state control in healthcare shall be performed in the form of inspections and other forms.

      Inspection shall be carried out in accordance with the Law of the Republic of Kazakhstan "On the state control and supervision in the Republic of Kazakhstan."

      Other forms of the state control shall be performed in accordance with this Code.

      4. A senior chief state inspector or a chief state healthcare inspector in the relevant area before making a decision on an application (complaint) of individuals and (or) legal entities against actions (inaction) or acts, may suspend, cancel or revoke the acts of an inferior chief state inspector or chief state healthcare inspector.

      5. The state bodies, conducting the state control and supervision in healthcare, shall develop and approve the forms of mandatory departmental accountability, checklists, risk assessment criteria, semi-annual plans for inspections in accordance with the Law of the Republic of Kazakhstan "On State Control and Supervision in the Republic of Kazakhstan".

      Footnote. Article 19 as amended by the Laws of the Republic of Kazakhstan dated on 19.03.2010 No 258-IV; dated on 06.01.2011 No 378-IV (shall be enforced upon expiration often calendar days after its first official publication); dated on 10.07.2012 No 36-V (shall be enforced upon expiration often calendar days after its first official publication).

**Article 20. The state control in medical services area**

      1. The state control in medical services area is aimed at prevention, detection, suppression of violations of legislation of the Republic of Kazakhstan in medical services, as well as monitoring of healthcare subjects’ compliance with the regulations in medical services area.

      2. The objects of the state control in medical services area shall be the medical services rendered by individuals and legal entities.

      3. The state control in medical services shall be conducted in the form of inspections and other forms of supervision.

      An inspection shall be carried out in accordance with the Law of the Republic of Kazakhstan "On State Control and Supervision in the Republic of Kazakhstan."

      Other forms of the state control shall be carried out in accordance with this Code.

      4. The officials responsible for the state control in medical services area shall be:

      1) the Chief state inspector for control over the medical services area in the Republic of Kazakhstan and his deputies;

      2) the state inspectors for control over the medical services provision;

      3) the chief state inspectors for control in medical services areas of regions, a city of republican status and the capital, and their deputies;

      4) the state inspectors for control over medical services of regions, a city of republican status and the capital.

      5. The citizens of the Republic of Kazakhstan with a medical degree shall be appointed to the positions of the heads of the state bodies to conduct the state control in medical services area and healthcare organizations.

      6. The chief state inspector of the Republic of Kazakhstan for control over medical services, on the basis of an inspection results, may issue instructions to the head of local state body for healthcare management of regions, a city of republican status and the capital.

      7. The officials, conducting the state control in medical services shall have a right:

      1) to issue instructions to the healthcare subjects on elimination of violations of the legislature legislation of the Republic of Kazakhstan on healthcare;

      2) to request and obtain the necessary information from the healthcare subject on medical care, provided to the population;

      3) to make copies of the documents required for inspection in medical services area;

      4) to initiate suspension of an accreditation certificate for up to six months and its revocation in accordance with the legislature of the Republic of Kazakhstan on administrative offences;

      5) to consider cases on administrative offenses and impose administrative penalties for violating the legislature of the Republic of Kazakhstan on healthcare within their competence;

      6) to initiate suspension of a license for medical activities in accordance with the legislature of the Republic of Kazakhstan on administrative offences;

      7) to initiate revocation of a license for medical activities in accordance with the legislature of the Republic of Kazakhstan on administrative offences;

      8) to initiate suspension and revocation of a specialist certificate in the order, prescribed by the laws of the Republic of Kazakhstan;

      9) to apply to the court for individuals’ and legal entities’ non-performance or improper performance of legal requirements or regulations, decrees, issued by the officials of the authorized body;

      10) to take measures to suspend the activities or certain types of activities of an individual entrepreneur or a legal entity in accordance with the legislature of the Republic of Kazakhstan on administrative offences.

      8. The decisions, made by the officials responsible for the state control in medical services area shall be obligatory for implementation by the healthcare subjects and may be appealed to a higher authority and (or) in the courts.

      Footnote. Article 20 as amended by the Law of the Republic of Kazakhstan, dated on 06.01.2011 No 378-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 21. The state healthcare and epidemiological surveillance**

      1. The state healthcare and epidemiological supervision shall be aimed at prevention, detection, suppression of violations of legislation of the Republic of Kazakhstan in healthcare and epidemiological welfare of the population, as well as monitoring of observance of the regulations in healthcare and epidemiological safety and health standards in order to protect people’s health and environment.

      2. The objects of the state healthcare and epidemiological supervision shall be the individuals and legal entities, houses, buildings, industrial facilities, products, equipment, vehicles, water, air, food, and other objects, the functioning, use, consumption and exploitation of which could harm human health and the environment.

      The list of objects and products, subject to the state healthcare and epidemiological supervision shall be defined by the authorized body.

      3. The state control in healthcare and epidemiological welfare of the population shall be performed in the form of inspections and other forms.

      An inspection shall carried out in accordance with the Law of the Republic of Kazakhstan "On state control and supervision in the Republic of Kazakhstan."

      Other forms of control in healthcare and epidemiological surveillance shall be carried out in accordance with the principle of necessity and sufficiency without visiting the objects (entities), except for the cases:

      if the visit is associated with obtaining permits, with the obligatory notification of legal statistics bodies at the location of the object (the subject) one day before the visit;

      in conducting epidemiological surveillance in the event of infectious and parasitic diseases, food poisoning of individuals (at home), for organizing and taking of healthcare-epidemiological (preventive) measures.

      4. The officers of the healthcare-epidemiological service authorized in accordance with this Code to perform the state healthcare and epidemiological supervision shall be:

      1) the Chief state healthcare inspector of the Republic of Kazakhstan and his deputies;

      2) the heads and specialists of the state body for healthcare and epidemiological welfare of the population;

      3) the heads of territorial subdivisions of the state body for healthcare and epidemiological welfare of the population in the relevant areas and transport – the chief state healthcare inspectors in the relevant areas and transport, their deputies and experts;

      4) the heads and specialists of departments of other state bodies, working in healthcare and epidemiological welfare of the population.

      5. The heads of other government agencies’ departments for healthcare and epidemiological welfare of the population shall be appointed and dismissed in accordance with legislation of the Republic of Kazakhstan in consultation with the Chief state healthcare inspector of the Republic of Kazakhstan.

      6. The citizens of the Republic of Kazakhstan with the higher medical education of healthcare-epidemiological profile shall be appointed to the positions of the heads of state bodies and organizations of healthcare-epidemiological service.

      7. The officials of the authorized body shall be entitled:

      1) to prohibit importation, manufacture, use and sale of products in the territory of the Republic of Kazakhstan intended for the use and application by the population, business and (or) other activities, in the order, approved by the Government of the Republic of Kazakhstan;

      2) to prohibit or suspend the use of baby foods, nutritional and dietary supplements, genetically modified objects, materials and articles, contacting with water and food, chemicals, certain types of products and substances that have harmful effects on human health;

      3) to call individuals and officials of legal entities to the healthcare-epidemiological service bodies to consider violations of the legislature of the Republic of Kazakhstan on healthcare and epidemiological welfare of the population;

      4) to pass resolutions on temporary suspension from work of persons, belonging to the decreed groups that are the source of infectious and parasitic diseases, as well as those, who have not passed the required medical examinations in time;

      5) to set up restrictive measures, including quarantine at the selected objects, in the manner, approved by the Government of the Republic of Kazakhstan;

      6) to send the persons, who are the potential sources of infectious and parasitic diseases, and those, who have contacted with the infectious patients, to the medical examination with temporary suspension from work until the results of laboratory tests received;

      7) upon medical indications to hospitalize the persons who are the sources of infectious and parasitic diseases;

      8) to require mandatory vaccination of the population, preventive and focal disinfection, disinfestation and deratization in premises and in vehicles, territories, in the focus of infectious and parasitic diseases;

      9) to suspend certain types of works, exploitation of acting, under-construction and reconstructed objects in accordance with legislation of the Republic of Kazakhstan on administrative offences before elimination of violations of legal acts in healthcare-epidemiological and hygienic standards;

      10) to prohibit manufacturing, use and sale of new raw materials, products, chemicals, equipment, tools, processes, instruments if they are found to be dangerous to life and health;

      11)

excluded by the Law of the Republic of Kazakhstan, dated on 10.07.2012 No 36-V (shall be enforced upon expiration often calendar days after its first official publication);

      12) to request materials for healthcare-epidemiological expertise, required to assess the impact of the examined object on the environment and human health, as well as to take samples and select samples of products in sufficient quantities and not exceeding the amount necessary to carry it out, without reimbursement of this product’s cost;

      13) to make demands on harmonization of the regulations on healthcare-epidemiological welfare of the population with the legislation of the Republic of Kazakhstan on healthcare and epidemiological welfare of the population;

      14) to conduct radiation monitoring in healthcare and epidemiological welfare of the population in the territory of the Republic of Kazakhstan;

      15) to establish healthcare-protection zones and resize them;

      16)

excluded by the Law of the Republic of Kazakhstan, dated on 15.07.2011 No 461-IV (shall be enforced from 30.01.2012).

      17) to monitor introduction and application of disinfection, disinfestation, deratization devices and dietary supplements;

      18) to apply to the court for individuals’ and legal entities’ non-performance or improper performance of requirements or instructions, decisions, issued by the officials of the healthcare-epidemiological service;

      19) to suspend a license for healthcare-hygienic and anti-epidemic medical activities in accordance with legislation of the Republic of Kazakhstan on administrative offences;

      20) to prohibit sale of non-iodized salt, except for the cases, established by the Government of the Republic of Kazakhstan.

      8. Before making a decision, based on the results of a state healthcare-epidemiological supervision, depending on the revealed violations of the legislation of the Republic of Kazakhstan in healthcare and epidemiological welfare, the officials of healthcare-epidemiological service, in addition to the acts, defined in the Code of the Republic of Kazakhstan on administrative violations, shall issue the following acts:

      1) an act of healthcare-epidemiological inspection - a document, issued by an official, conducting a state healthcare and epidemiological supervision upon the inspection results of the object’s compliance with the requirements of the legislature of the Republic of Kazakhstan in healthcare and epidemiological welfare of the population;

      2) an instruction on elimination of violations of the legislation of the Republic of Kazakhstan in healthcare and epidemiological welfare of the population;

      3) a decision of the Chief state healthcare inspector of the Republic of Kazakhstan on imposition of a disciplinary penalty on officials of state bodies and healthcare-epidemiological organizations;

      4) the decision of the chief state healthcare inspectors on:

      organization of healthcare and anti-epidemiological (preventive) measures;

      temporary suspension of individuals from work;

      prohibition of import, manufacturing, use and sale of products intended for use and application by the population, business and (or) other activities;

      prohibition of production, use and sale of new raw materials, products, chemicals, equipment, tools, processes, instruments, if they are found to be dangerous to life and health;

      suspension of activities or certain types of activities of an individual entrepreneur or a legal entity in accordance with the legislature of the Republic of Kazakhstan on administrative offences.

      Footnote. Article 21 as amended by the Laws of the Republic of Kazakhstan dated on 06.01.2011 No 378-IV (shall be enforced upon expiration often calendar days after its first official publication); dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011); dated on 15.07.2011 No 461-IV (shall be enforced from 30.01.2012); dated on 10.07.2012 No 36-V (shall be enforced upon expiration often calendar days after its first official publication.)

**Article 22. The state control in circulation of drugs, medical devices and medical equipment**

      1. The state control in circulation of drugs, medical devices and medical equipment shall be aimed at prevention, detection, suppression of violations of the legislature of the Republic of Kazakhstan in circulation of drugs, medical devices and medical equipment, as well as control of observance of the legal regulatory acts, regulating circulation of drugs, medical devices and medical equipment in the Republic of Kazakhstan.

      2. The objects of the state control in circulation of drugs, medical devices and medical equipment are the circulations of drugs, medical devices and medical equipment.

      3. The state control in circulation of drugs, medical devices and medical technology shall be performed in the form of inspections and other forms.

      Inspection shall be carried out in accordance with the Law of the Republic of Kazakhstan "On state control and supervision in the Republic of Kazakhstan."

      Other forms of control shall be carried out in accordance with this Code.

      4. The officials, responsible for the state control in circulation of drugs, medical supplies and medical equipment shall be:

      1) the Chief state pharmaceutical inspector of the Republic of Kazakhstan and his deputies;

      2) the state pharmaceutical inspectors;

      3) the chief state pharmaceutical inspectors of regions, towns of republican significance and the capital and their deputies;

      4) the state pharmaceutical inspectors of regions, towns of republican significance and the capital.

      5. The officials responsible for the state control in circulation of drugs, medical devices and medical equipment might be the citizens of the Republic of Kazakhstan with higher pharmaceutical education.

      6. The officials of the authorized body shall be entitled:

      1) to take samples of drugs, medical devices and medical equipment for examination, in sufficient quantities and not exceeding the amounts necessary to conduct it, without reimbursement of the product’s cost in the manner, defined by the authorized body;

      2) to prohibit import, production, manufacturing, storage, use and sale in the territory of the Republic of Kazakhstan of the drugs, medical devices and medical equipment, that are degraded, counterfeit, expired, and those that do not comply with the requirements of the legislation of the Republic of Kazakhstan in healthcare area;

      3) to issue instructions on elimination of violations in circulation of drugs, medical devices and medical equipment;

      4) to suspend a license for pharmaceutical activity for up to six months in accordance with legislation of the Republic of Kazakhstan on administrative offences;

      5) to initiate revocation of a license for pharmaceutical activity in accordance with legislation оf the Republic of Kazakhstan on administrative offences;

      6) to apply to the court for individual’s and legal entities’ non-performance or improper performance of requirements or instructions, decisions, issued by the officials of the authorized body;

      7) to visit objects where pharmaceutical activities are conducted to inspect observance of the requirements of the Laws of the Republic of Kazakhstan and resolutions of the Government of the Republic of Kazakhstan on circulation of drugs, medical devices and medical equipment;

      8) to obtain information and reports on circulation of drugs, medical devices and medical equipment from the subjects, involved in circulation of drugs, medical devices and medical equipment.

      Footnote. Article 22 is in the wording of the Law of the Republic of Kazakhstan, dated on 10.07.2012 No 36-V (shall be enforced upon expiration of ten calendar days after its first official publication.)

 **Chapter 6. FUNDING OF THE HEALTHCARE SYSTEM**

**Article 23. Sources of financial support for the healthcare system**

      1. The sources of financial support for the healthcare system shall be:

      1) the budget funds;

      2) the funds of voluntary insurance;

      3) the funds received for rendering of the paid services;

      4) other sources, not contradicting the legislation of the Republic of Kazakhstan.

      2. The procedure of tariff formation and expenditure planning for medical services, rendered within the guaranteed volume of free medical care shall be defined by the authorized body.

      3. Funding of expenditures for the guaranteed volume of free medical care shall be performed in accordance with the legislature of the Republic of Kazakhstan.

**Article 24. Forms of financing of healthcare organizations, providing a guaranteed volume of free medical care**

      Financing of healthcare organizations that provide a guaranteed volume of free medical care shall be carried out:

      1) for public healthcare organizations - on an individual plan of financing;

      2) for healthcare organizations, except for the state organizations - on a contract basis with the administrators of budget programs.

**Article 25. Use of sources of financial support of healthcare system**

      1. The funds of the healthcare system shall be spent on:

      1) reimbursement of expenditures for provision of the guaranteed volume of free medical care;

      2)

excluded by the Law of the Republic of Kazakhstan, dated on 03.07.2013 No 124-V (shall be enforced upon expiration of ten calendar days after its first official publication);

      3) material and technical equipment of healthcare organizations;

      4) acquisition of drugs, orphan drugs, blood and its components, vaccines and other immunotherapeutic drugs, as well as medical devices and medical equipment;

      5) elimination of cases and epidemics of infectious diseases;

      6) training, career development and retraining of medical and pharmaceutical personnel;

      7) development and introduction of medical science achievements;

      8) other expenses that are not prohibited by the legislation of the Republic of Kazakhstan.

      2. The procedure for reimbursement of healthcare organizations’ expenditures at the expense of budget funds shall be defined by the Government of the Republic of Kazakhstan.

      3. Reimbursement shall be made taking into account the results of quality control and the volume of the rendered medical assistance, conducted by the authorized body.

      Footnote. Article 25, as amended by the Law of the Republic of Kazakhstan, dated on 03.07.2013 No 124-V (shall be enforced upon expiration of ten calendar days after its first official publication).

 **Chapter 7. INFORMATISATION IN HEALTHCARE AREA**

**Article 26. Objects and subjects of informatization in healthcare**

      1. The objects of information in healthcare shall be the electronic information resources, information systems and electronic healthcare services.

      2. The subjects of informatization in healthcare shall be the state bodies, individuals and legal entities, working or establishing legal relations in informatization area in healthcare.

      3. The activities in informatization in healthcare shall include development of information and communication infrastructure of the healthcare branch in the frames of "electronic government", providing individuals and legal entities with medical and statistical information, as well as provision of other e-services.

**Article 27. Principles of informatization in healthcare area**

      Informatization in healthcareshall be based on the following principles:

      1) standardization and formalization of administrative processes at all levels of management, development and implementation of a unified policy for healthcare management;

      2) a widespread use of international standards in healthcare and informatization;

      3) free access to electronic information resources, containing data on work of agencies and healthcare organizations, except for the electronic information resources, access to which is limited in accordance with legislation of the Republic of Kazakhstan;

      4) timeliness, objectivity, completeness and reliability of electronic information resources, public dissemination of which is mandatory;

      5) ensuring safety and privacy of the data of healthcare information resources;

      6) confidentiality of electronic information recourses, containing personalinformation of individuals (patients) and patient’s access to the personal information;

      7) ensuring movement of medical information after the patient.

      Footnote. Article 27, as amended by the Law of the Republic of Kazakhstan, dated on 21.05.2013 No 95-V (shall be enforced upon expiration of six months after its first official publication).

**Article 28. Ensuring confidentiality of information about individuals (patients)**

      1. Electronic information resources of healthcare, containing personal information about individuals (patients) shall be classified as the confidential electronic information resources, receiving, processing and use of which shall be limited by the purposes for which they are collected.

      2. Collecting, processing of personal data for the formation of electronic information resources, containing personal data of individuals (patients), shall be carried out with the consent of individual (patient) or his legal representative, unless otherwise provided by this Code or other Laws of the Republic of Kazakhstan.

      3. Owners and keepers of information systems, that received electronic information resources, containing personal medical data, shall be obliged to take measures to protect them. Such an obligation shall arise from receipt of electronic information resources, containing personal data of individuals (patients), and until their amortization or a depersonalization or until the receipt of consent for their disclosure from the person to whom personal data relates.

      4. Use of electronic information resources, containing personal medical information about individuals (patients) shall not allowed for causing property and (or) moral damage, limiting the rights and freedoms, guaranteed by the Laws of the Republic of Kazakhstan.

      5. Access of medical personnel to electronic information resources, containing personal medical information of individuals (patients) should be limited for providing medical care to an individual (patient) only.

      Footnote. Article 28 is in the wording of the Law of the Republic of Kazakhstan; dated on 21.05.2013 № 95-V (shall be enforced upon expiration of six months upon its first official publication).

 **Chapter 8. INTERNATIONAL COOPERATION IN HEALTHCARE AREA**

**Article 29. Priorities and directions of international cooperation in healthcare area**

      1. The priorities of international cooperation in healthcare shall be:

      1) protection of interests of the Republic of Kazakhstan and its people in healthcare area;

      2) provision of epidemiological safety of the Republic of Kazakhstan;

      3) application of rules and principles of international law to address healthcare issues at the interstate level;

      4) formation of a healthy lifestyle and healthy food.

      2. The directions of international cooperation in healthcare shall be:

      1) participation in international healthcare initiatives;

      2) attraction and provision of technical assistance in healthcare at the international level;

      3) sending of the citizens of the Republic of Kazakhstan for a medical treatment abroad and provision of medical assistance to foreign nationals;

      4) introduction of international innovation technologies and upgrade of the healthcare system;

      5) integration into the global medical science;

      6) ensuring access of medical and pharmaceutical workers to information and intellectual resources;

      7) inter-state cooperation in training, career development and retraining of medical and pharmaceutical personnel;

      8) provision of international healthcare assistance in emergency situations;

      9) exchange of information, technologies in circulation of drugs, medical devices and medical equipment and harmonization of requirements to safety and quality of pharmaceutical and medical products;

      10) healthcare protection of the borders, safety of the imported products.

**Article 30. Economic and legal framework for international cooperation in healthcare area**

      1. The economic basis for international cooperation in healthcare shall be:

      1) compulsory and voluntary contributions to international organizations;

      2) participation in financing of international projects and events;

      3) attraction and use of grants;

      4) funding in accordance with the concluded international treaties.

      2. The legal framework for international cooperation in healthcare shall be the international treaties and agreements.

 **SPECIAL PART**

 **SECTION 2. HEALTHCARE SYSTEM AND ORGANIZATION OF MEDICAL ASSISTANCE**

 **Chapter 9. HEALTHCARE SYSTEM AND ORGANIZATION OF MEDICAL ASSISTANCE**

**Article 31. The structure of the healthcare system**

      1. The healthcare system shall consist of public and private healthcare sectors.

      2. The public healthcare sector shall consist of the state healthcare bodies, healthcare organizations, established on the right of the state ownership.

      3. The non-state sector of health care consists of health care organizations, based on the right of a private property, as well as individuals, practising private medicine and pharmaceutical activity.

      The list of diseases, the treatment of which is prohibited in the non-state healthcare sector shall be defined by the authorized body.

**Article 32. Healthcare subjects**

      1. Healthcare subjects shall be the healthcare organizations, as well as the individuals, engaged in private medical practice and pharmaceutical activity.

      2. The healthcare system shall have the following healthcare organizations:

      1) the organizations, providing outpatient assistance;

      2) the organizations, providing inpatient assistance;

      3) the organizations of emergency medical assistance and air ambulance;

      4) the organizations of emergency medicine;

      5) the organizations of medical rehabilitation;

      6) the organizations, providing palliative and nursing care;

      7) the organizations, providing blood supply services;

      8) the organizations, engaged in forensic medicine and pathoanatomy;

      9) the healthcare organizations, involved in pharmaceutical activities;

      10) the healthcare organizations, involved in healthcare and epidemiological welfare of the population;

      11) scientific healthcare organizations;

      12) education organizations in healthcare area;

      13) the healthcare organizations, promoting healthy lifestyle and healthy eating;

      14) the healthcare organizations, involved in HIV / AIDS prevention;

      14-1) organizations of sports medicine;

      15) national holdings.

      3. The authorized body shall develop and approve:

      1) the list of healthcare organizations and regulations on their activities;

      2) the range and qualification characteristics of the medical and pharmaceutical professions and positions of health professionals;

      3) the structure, typical staffing and HR standards of healthcare organizations;

      4) the order of interaction between healthcare organizations.

      4. Individuals shall have the right to engage in private medical practice if they have a relevant certificate, work experience of at least five years in this profession and a corresponding license.

      Footnote. Article 32, as amended by the Law of the Republic of Kazakhstan, dated on 27.04.2012 No 15-V (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 33. Organization of medical assistance**

      1. Organization of medical assistance shall be carried out by the authorized body, local state bodies for healthcare management of regions, city of republican status and the capital, the provision of medical assistance – by the healthcare entities in the order, defined by this Code.

      2. Healthcare subjects shall provide:

      1) high-quality medical care in accordance with the license;

      2) application of the methods of diagnosis, prevention and treatment as well as the drugs, approved by the authorized body;

      3) readiness to work in emergency situations, armed conflicts and terrorist acts;

      4) prevention, diagnosis and treatment of diseases that are dangerous to others, as well as occupational diseases;

      5) the citizens with free, timely and reliable information on the types and forms of medical care;

      6) observance of regulations in healthcare and epidemiological welfare of the population and health standards;

      7) collaboration with other healthcare organizations and continuity of activities;

      8) promotion of a healthy lifestyle and healthy eating;       9) maintenance of primary medical records, and reporting on the forms, types, volumes, and deadlines, established by the authorized body;

      10) the information to the authorized body on the cases of infectious diseases, poisoning, mental and behavioral disorders (diseases) that are dangerous to others, to the emergency bodies - about a threat of occurrence and (or) occurrence of medical-healthcare consequences of emergencies, to the law enforcement bodies - information about persons that have applied because of new traumas, injuries, criminal abortions, and diseases, dangerous to others.

      Footnote. Article 33, as amended by the Laws of the Republic of Kazakhstan, dated on 19.03.2010 No 258-IV; dated on 08.04.2010 No 266-IV (the order of enforcement see Article 2).

**Article 34. The guaranteed volume of free medical care**

      1. The guaranteed volume of free medical care shall be provided to the citizens of the Republic of Kazakhstan and repatriates at the expense of budget funds and shall include preventive, diagnostic and therapeutic medical services with the greatest proven efficiency, according to the list, approved by the Government of the Republic of Kazakhstan.

      2. The guaranteed volume of free medical care shall include:

      1) emergency care and air ambulance;

      2) outpatient care, including:

      primary health care;

      consultative and diagnostic assistance on a primary care specialist’s referral and specialized professionals;

      3) inpatient medical assistance on a primary healthcare specialist’s referral or medical organization in the frames of the planned number of hospitalizations (maximal volumes), defined by the authorized body, for emergency indications - regardless of the presence of a referral;

      4) hospital replacing medical care on a referral of a primary healthcare specialist or medical organization;

      5) rehabilitation treatment and medical rehabilitation;

      6) palliative and nursing care for the groups of population, defined by the Government of the Republic of Kazakhstan.

      3. Drugs for the guaranteed volume of free medical care shall be provided:

      1) in emergency medical assistance, outpatient and inpatient care - in accordance with the defined medical organizations and the drug formulary, conferred with the authorized body in the established order;

      2) in outpatient care – in accordance with the list of drugs and specialized medical products, which shall be approved by the authorized body for free and (or) preferential provision of certain categories of people with certain diseases (health statuses).

      4. Selection of a provider of the guaranteed volume of free medical care and reimbursement of his expenses shall be performed by the administrators of relevant budget programs in the manner, defined by the Government of the Republic of Kazakhstan.

      5. Preferential right to conclude contracts for the guaranteed free medical care belongs to the accredited healthcare organizations.

      Footnote. Article 34, as amended by the Law of the Republic of Kazakhstan, dated on 28.06.2012 No 22-V (shall be enforced from 01.07.2012).

**Article 35. The grounds and procedure for obtaining the paid medical services**

      1. The paid medical services shall be provided by public and private healthcare organizations, the individuals, engaged in private medical practice, if the profile of disease corresponds with the license for medical activity.

      2. The paid medical services shall be rendered during:

      1) the primary healthcare assistance, diagnostic and treatment services at the initiative of the patients, including without a referral of primary healthcare specialists and healthcare organizations;

      2) the treatment with the drugs, that are not included in the drug formulary;

      3) medical examinations, that are not included in the list of the guaranteed volume of free medical care;

      4) sanatorium therapy without the proper referral;

      5) medical and genetic researches without medical indications;

      6) medical examination of citizens for employment and training;

     7) medical care under a contract with an organization, including voluntary insurance;

      8) provision of additional services;

      9) medical assistance to foreigners and stateless persons, except for the cases, specified in paragraph 5 of Article 87 of this Code.

      3. The paid medical services shall be provided on the basis of a contract, concluded between the patient and the healthcare subject, rendering these services.

      The contract for rendering of the paid medical services shall contain the following basic conditions:

      1) the types and amount of medical assistance;

      2) the deadlines for medical care;

      3) the tariffs for medical and non-medical services and procedures for their payment;

      4) the rights and obligations of the parties;

      5) the order of making changes, additions, and termination of the contract;

      6) establishment of civil liability of the parties for any failure to perform contractual obligations.

      4. The types of the paid services and a price list shall be advertised to the population through visual information in the public and private healthcare organizations and in the individuals’ offices, engaged in private medical practice.

      5. In public healthcare organizations, the prices for the paid services shall be calculated taking into account all expenses, associated with rendering of medical and other services, and other additional costs and may be revised twice a year only.

      Prices for the paid services shall not be below the tariff of a similar medical service, established by the administrator of budget programs for the guaranteed volume of free medical care.

      6. Keeping of records and reports on rendering the paid medical services shall be carried out in accordance with the forms, established by the authorized body.

      7. A healthcare organization shall be responsible for the timely and proper provision of the paid medical services to the citizens from the time they applied for treatment in the manner, specified by the Laws of the Republic of Kazakhstan.

      8. The procedure and conditions for rendering the paid medical services in healthcare organizations shall be defined by the Government of the Republic of Kazakhstan.

 **SECTION 3. MEDICAL ACTIVITY**

 **Chapter 10. CONTENT AND TYPES OF MEDICAL ACTIVITY**

**Article 36. The content of medical activity**

      Medical activity shall include professional activity of individuals with higher or vocational secondary medical education, as well as the legal entities, working in healthcare area.

**Article 37. The types of medical activity**

      The following types of medical activities shall be performed in the Republic of Kazakhstan:

      1) healthcare assistance;

      2) laboratory diagnosis;

      3) pathologicoanatomic diagnosis;

      4) banking of blood and its components;

      5) healthcare and epidemiological welfare of the population;

      6) public health protection;

      7) educational and scientific activities in healthcare area;

      8) expertise in healthcare area;

      9) other types of activities, not prohibited by this Code.

 **Chapter 11. MEDICAL ASSISTANCE**

**Article 38. The types of medical assistance**

      The main types of medical assistance shall be:

      1) pre-hospital medical care;

      2) adequate medical assistance;

      3) specialized medical assistance;

      4) highly skilled medical care;

      5) medical and social assistance.

**Article 39. Pre-hospital medical care**

      1. Pre-hospital medical care - the medical care, rendered by medical personnel with secondary medical education for prevention of diseases, as well as in diseases that do not require the use of methods of diagnosis, treatment and rehabilitation with the participation of a physician.

      2. In emergency cases, the pre-hospital medical care may be provided by the persons without medical education (paramedics), who have passed appropriate training in the order, defined by the authorized body, as well as by other persons in order to save the lives of the injured.

      3. The types and amount of pre-hospital medical assistance shall be defined by the authorized body.

**Article 40. Adequate medical assistance**

      1. Adequate medical assistance - the medical care, provided by medical personnel with higher medical education for the diseases that do not require the specialized methods of diagnosis, treatment and medical rehabilitation.

      2. The types and amount of the adequate medical assistance shall be defined by the Government of the Republic of Kazakhstan.

      Footnote. Article 40, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 41. The specialized medical assistance**

      1. Specialized medical assistance - the medical care provided by profile specialists for the diseases that require special methods of diagnosis, treatment and rehabilitation.

      2. The specialized medical assistance shall be provided by multi-profile healthcare organizations in the form of consultative and diagnostic or inpatient medical care.

      3. The types and amount of the specialized medical assistance shall be defined by the authorized body and local state bodies for healthcare management of regions, city of republican significance and the capital.

**Article 42. Highly skilled medical care**

      1. Highly skilled medical care - the medical assistance, provided by the profile specialists for the diseases that require the use of modern technologies for diagnosis, treatment and rehabilitation in medical organizations, defined by the authorized body.

      2. Coordination of the medical organizations, providing highly skilled medical care shall be performed by the authorized body.

      3. The types and amount of a highly skilled medical care shall be defined by the Government of the Republic of Kazakhstan.

      Footnote. Article 42, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 43. Medical and social assistance**

      1. Medical and social assistance - the medical care, provided by the profile specialists to the citizens, suffering from social diseases, the list of which shall be specified by the Government of the Republic of Kazakhstan.

      2. The procedure of medical and social assistance, provided to the citizens suffering from social diseases shall be defined by the Government of the Republic of Kazakhstan.

      Footnote. Article 43, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 44. The forms of providing medical assistance**

      Medical assistance may be provided in the following forms:

      1) outpatient care:

      primary medical care;

      consultative and diagnostic assistance;

      2) inpatient assistance;

      3) hospital-replacing assistance;

      4) emergency medical assistance;

      5) the air ambulance;

      6) medical care in emergency situations;

      7) rehabilitation and medical rehabilitation;

      8) palliative and nursing assistance;

      9) traditional medicine, alternative medicine (healing).

**Article 45. Primary health care**

      1. Primary health care - a pre-medical or qualified medical assistance without a round-the-clock medical supervision, including a range of available medical services, provided to an individual, a family and society:

      1) diagnosis and treatment of common diseases and injuries, poisonings and other emergencies;

      2) healthcare and anti-epidemic (preventive) measures in the outbreaks of infectious diseases;

      3) hygienic education of the population, protection of family, motherhood, fatherhood and childhood;

      4) outreach work for safe water supply and nutrition education of the population.

      2. Primary medical care shall be provided by general practitioners, pediatricians, primary care physicians, medical assistants, obstetricians and nurses.

      3. The work of the primary healthcare organizations shall be based on the territorial principle in order to ensure access to medical care of the citizens at their place of residence and (or) their attachment, taking into account the right for free choice of a medical organization.

      4. The types, the volume, the order of primary health care, as well as the procedure for attachment of the citizens to the primary healthcare institutions shall be defined by the Government of the Republic of Kazakhstan.

      5. Organization of primary health care shall be performed by the local state governing bodies.

      Footnote. Article 45 as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 46. Consultative and diagnostic assistance**

      1. Consultative and diagnostic assistance - the specialized or tertiary care without round-the-clock medical supervision.

      2. The order of providing consultative and diagnostic services shall be defined by the Government of the Republic of Kazakhstan.

      Footnote. Article 46, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 47. Inpatient care**

      1. Inpatient care - a form of a qualified, specialized and highly skilled medical care with twenty-four-hour medical supervision.

      2. Healthcare organizations, that provide inpatient care, shall ensure appropriate care and nutrition.

      3. The order of inpatient care shall be established by the Government of the Republic of Kazakhstan.

      Footnote. Article 47, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 48. Hospital replacing assistance**

      1. Hospital replacing assistance - a form of a pre-hospital, qualified, specialized and highly skilled medical care with the medical supervision, lasting four-eight hours a day.

      2. The order of providing the hospital replacing assistance shall be defined by the Government of the Republic of Kazakhstan.

      Footnote. Article 48, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 49. Emergency medical assistance**

      1. Emergency medical assistance - a form of medical care in the event of diseases and conditions, requiring emergency medical care to prevent significant harm to the health or eliminate a threat to life.

      2. In order to provide emergency medical care, the specialized organizations and emergency medical services shall be created in the manner, defined by legislation of the Republic of Kazakhstan in healthcare area.

      3. The procedure for emergency medical assistance shall be specified by the Government of the Republic of Kazakhstan.

      Footnote. Article 49, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 50. Air ambulances**

      1. Air ambulances - a form of emergency medical care which shall be provided if medical care is impossible because of absence of medical equipment or professionals of relevant qualifications in the medical organization at the location of the patient. The medical care in the form of air ambulance shall be carried out via delivery of qualified professionals to the destination point or transportation of the patient to the appropriate medical organization by various types of transport.

      2. The procedure for providing medical assistance in the form of air ambulance shall be defined by the Government of the Republic of Kazakhstan.

      Footnote. Article 50, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 51. Medical care in emergencies**

      1. Medical care in emergency situations -a form of medical assistance of emergency medicine in natural and man-made emergency situations.

      2. The order of providing, the types and amount of medical assistance in emergency situations shall be defined by the Government of the Republic of Kazakhstan.

      Footnote. Article 51 as amended by the Constitutional Law of the Republic of Kazakhstan dated on 03.07.2013 No 121-V (shall be enforced upon expiration of ten calendar days after its first official publication).

**Article 52. Rehabilitation and medical rehabilitation**

      1. Rehabilitation and medical rehabilitation shall be provided to the citizens suffering from congenital and evoked diseases, and the effects of acute, chronic diseases and injuries.

      2. Rehabilitation and medical rehabilitation shall be performed in healthcare organizations, as well as sanatorium organizations.

      3. Citizens shall be given the vouchers for sanatorium treatment in accordance with the legislature of the Republic of Kazakhstan in healthcare area and the labor legislation of the Republic of Kazakhstan.

      4. The order of rehabilitation and medical rehabilitation, including the children's medical rehabilitation shall be defined by the Government of the Republic of Kazakhstan.

      Footnote. Article 52, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 53. Palliative and nursing care**

      1. Under the guidance of a physician, the palliative care shall be provided in the specialized structural units, independent medical organizations (hospices) or in the form of home care to the incurable patients with the terminal (final) stage of the disease.

      2. Nursing care shall be provided in the cases, when medical supervision shall not be required, in specialized structural units, independent healthcare organizations (hospitals of nursing care) or in the form of home care.

      3. The order of palliative and nursing care shall be defined by the Government of the Republic of Kazakhstan.

      Footnote. Article 53, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 54. Traditional medicine, alternative medicine (healing)**

      1. The methods of traditional medicine shall include homeopathy, hirudotherapy, manual therapy, zone therapy, herbal medicine and treatment by natural medications.

      2. Individuals with medical education and a relevant license shall have the right to work in traditional medicine area.

      3. Alternative medicine (healing) - a set of accumulated empirical knowledge about the healing methods, as well as the medical and hygienic techniques and skills and their practical application to preserve health, prevent and treat diseases.

      4.

excluded by the Law of the Republic of Kazakhstan, dated on 10.07.2012 No 36-V (shall be enforced upon expiration of ten calendar days after its first official publication.)

      5. Conduction of mass healing sessions, including through the media shall be prohibited.

      Footnote. Article 54, as amended by the Law of the Republic of Kazakhstan, dated on 10.07.2012 No 36-V (shall be enforced upon expiration often calendar days after its first official publication.)

**Article 55. Laboratory diagnostics**

      1. Laboratory diagnostics - a complex of medical services, aimed at confirming presence or absence of disease (status) through laboratory testing of biomaterials, taken from patients.

      2. Regulations on the activities of organizations and (or) structural units of healthcare organizations, performing laboratory diagnostics, as well as the amount and the types of the tests, shall be defined by the Government of the Republic of Kazakhstan.

      Footnote. Article 55, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 56. Pathologicoanatomic diagnostics**

      1. Pathologicoanatomic diagnostics shall be performed to make a diagnosis via analyzing a complex of changes in the tissues and organs of a corpse during its postmortem examination, as well as in the organs (fragments of organs) and tissues, taken out via surgery and (or) biopsy, and shall be based on the results of direct examination (macroscopic studies), the researches, made by magnifying arrangement (microscopic examination), other technologies, as well as clinical and anatomical comparisons.

      2. Postmortem examination shall be performed to ascertain the cause of death and the diagnosis.

      If there is no suspicion of violent death and if there is a written application from a spouse (wife), close relatives or legal representatives or a written will expression of a person, given while he was alive, the issuance of a corpse shall be permitted without a postmortem examination, except for the cases of maternal and infant mortality, and death from dangerous infections, with the issuance of the document certifying the fact of death, in the form, approved by the authorized body.

      At the request of a spouse (wife), close relatives or a legal representative of the deceased person, a postmortem examination may be performed by an independent (independent) expert (s) in the order, defined by the Government of the Republic of Kazakhstan.

      3. Regulations on the work of organizations and (or) structural units of healthcare organizations, performing postmortem examinations, as well as the order of postmortem examination shall be defined by the Government of the Republic of Kazakhstan.

      Footnote. Article 56, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

 **Chapter 12. TYPES OF EXPERTISE IN HEALTHCARE AREA**

**Article 57. An expertise in healthcare area**

      1. An expertise in healthcare - an integral part of public health protection.

      2. In the Republic of Kazakhstan, the following types of expertise in healthcare shall be performed:

      1) evaluation of quality of medical services;

      2) examination of temporary disability;

      3) military medical examination;

      4) forensic-medical, forensic psychiatric and forensic-drug examination;

      5) healthcare and epidemiological expertise;

      6) examination of medications, medical devices and medical equipment;

      7) scientific and medical expertise.

      3. Examination in healthcare, except for the examination of medications, medical devices and medical equipment in the state registration, re-registration and amending the registration dossier shall be performed by the individuals and legal entities, taking into account the relevant license and (or) a certificate of accreditation.

**Article 58. Examination of the quality of medical services**

      1. Examination of medical services’ quality - a set of organizational, analytical and practical actions, aimed at assessment of the quality of medical services, provided by the individuals and legal entities, using indicators that reflect the performance indexes, completeness and compliance of medical services with the standards.

      2. Examination of the quality of medical services shall be divided into internal and external ones.

      3. In order to conduct an internal examination, an internal control (audit) service shall be established in each medical organization. The structure and composition of the service shall be approved by the head of the organization, depending on the amount of the medical services provided.

      The internal control (audit) service shall analyze medical care, clinical operations of a healthcare organization, reveal violations in medical care provision and standards, and considerappeals of the treated patients within five days.

      Upon the results of the audit, the internal control (audit) service shall make proposals to the head of the medical organization to address the revealed problems and conditions, reducing the quality of medical services.

      4. External examination of quality of medical services shall be performed by the authorized body and (or) by independent experts.

      5. Organization and procedure of the internal and external examinations of quality of medical services shall be defined by the Government of the Republic of Kazakhstan.

      Footnote. Article 58, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 59. Examination of temporary disability**

      1. Examination of temporary disability shall be conducted to recognize officially a disability of an individual and his temporary release from work during the disease.

      2. The procedure of temporary disability examination, as well as issuance of a sick leave and a temporary work incapacity certificate shall be defined by the Government of the Republic of Kazakhstan.

      Footnote. Article 59, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 60. Military medical examination**

      1. Military medical examination shall be conducted to confirm medical fitness for military service in the Armed Forces, other troops and military units of the Republic of Kazakhstan or service in special state bodies, bodies of internal affairs, penal system, the firefighting service, the financial police, customs bodies, prosecutor's office (hereinafter - the military service or service in special state bodies and law enforcement agencies), as well as to define causation of diseases, injuries (wounds, injuries, contusions) (hereinafter - the injuries) and death in connection with performing (performance of duties ) military service or service in special state and law enforcement bodies and military duties.

      2. Military medical examination shall be carried out:

      1) for medical examination of:

      the citizens, attached to the enlistment offices, called up for military service or military duties and entering the military (special) schools, republican military boarding schools (lyceums);

      the citizens, applying for military service or service in special state and law enforcement agencies, including on the contract basis;

      the soldiers, performing military service under conscription or contract;

      the employees of special state bodies;

      the cadets of the military (special) schools, the schools of special state agencies, the cadets and attendees;

      the military servants (the servants of the Armed Forces), employees (workers) of special state agencies, selected for the service (work) and those, working with radioactive substances, ionizing radiation sources, the components of rocket fuel, sources of electromagnetic fields; the aircraft staff of the state aviation;

      the citizens in reserve when called up for military gatherings, the gatherings of the special state bodies or for military service, the service in special state bodies or for registration purposes;

      2) during psycho-physiological selection of citizens, entering military service in the special state and law enforcement agencies;

      3) in revealing causation of injuries, diseases of the military servants, employees of the special state bodies or the citizens, that passed military service (military gatherings) or service (gatherings) in special state and law enforcement agencies;

      4) in estimating the level of military fitness for military service or service in special state and law enforcement agencies at the time of their discharge from military service or service in special state and law enforcement agencies;

      5) in revealing causation of death (death) of military servants, and those, liable to military service, employees during the military service (military gatherings), or service in special state and law enforcement agencies or after discharge from military service (military gatherings) or service (gatherings) in special state bodies, law enforcement agencies, caused by injury, disease, received during the military service (military gatherings) or service (gatherings) in special state and law enforcement agencies.

      3. The military medical examination bodies shall conduct military medical expertise in the Armed Forces, other troops and military units of the Republic of Kazakhstan, special state and law enforcement bodies.

      Military medical examination for the special state bodies shall be conducted by the military physician expertise agencies of the national security bodies.

      4. The requirements to the fitness for military service in the Armed Forces, other troops and military units of the Republic of Kazakhstan, special state bodies, the bodies of internal affairs and state aviation, are approved by the central executive bodies for defense, interior bodies and the central government agency for the national security in consultation with the authorized body.

      Footnote. Article 60 as amended by the Law of the Republic of Kazakhstan, dated on 13.02.2012 No 553-IV (shall be enforced upon expiration often calendar days after its first official publication.)

**Article 61. Forensic medical, forensic psychiatric and forensic drug expertise**

      1. The procedural order of scheduling and conducting a forensic-medical, forensic-psychiatric, and forensic drug testing shall be established by the Criminal Procedure Code of the Republic of Kazakhstan, the Civil Procedure Code of the Republic of Kazakhstan, the Code of Republic of Kazakhstan on administrative offences.

      2. The procedure for organizing the mentioned types of forensic expertise and performance of forensic investigations shall be established by the legislation of the Republic of Kazakhstan on forensic activities.

**Article 62. Healthcare-epidemiological expertise**

      1. Healthcare-epidemiological expertise - a complex of organoleptic, healthcare-hygienic, epidemiological, microbiological, virologic, parasitologic, healthcare-chemical, biochemical, toxicological, radiological, radiometric, dosimetric measurements of physical factors, other researches and testing, and expertise of projects, conducted to assess compliance of the projects, products, works, services and objects of business and (or) other activity with the normative legal acts on healthcare-epidemiological and hygienic standards.

      2. Healthcare-epidemiological examination shall be conducted in the manner, defined by the authorized body, the bodies and organizations of healthcare-epidemiological service within their jurisdiction, upon the regulations and instructions of officials of healthcare-epidemiological service, customs bodies and the applications of individuals and legal entities.

      3. Healthcare-epidemiological expertise in examination of projects shall be carried out by the state bodies of healthcare-epidemiological service, in healthcare-epidemiological laboratory research – by the state organizations for healthcare-epidemiological service.

      4. Healthcare-epidemiological laboratory tests shall be a part of the healthcare-epidemiological expertise, related to organoleptic, hygienic, toxicological, healthcare, chemical, biochemical, microbiological, epidemiological, bacteriological, virologic and parasitologic laboratory studies, testing of caloric content and biological value of food products, measuring of noise, vibration, electromagnetic fields and the physical factors, radiation research, including radiometry and dosimetry.

      5. In order to conduct a healthcare-epidemiological expertise upon applications of individuals and legal entities, they shall provide funding and submit the required documentation.

      6. Healthcare-epidemiological expertise shall not be conducted if there is unfit food and food stock.

      7. Chemical and biological agents, recognized potentially hazardous to human health or the future generations upon the results of healthcare-epidemiological expertise or scientific examination, shall be prohibited for use in the Republic of Kazakhstan. Register of potentially hazardous chemical and biological substances, prohibited for use in the Republic of Kazakhstan, shall be published in the print media.

      8. The state bodies of healthcare-epidemiological service on the basis of test results, and other forms of control and healthcare-epidemiological expertise shall issue a healthcare-epidemiological conclusion on:

      1) placement, reconstruction and expansion of nuclear energy and industry objects, space and subsoil objects, having emissions of chemical and biological agents into environment, physical factors, objects in ecological disaster zones and the objects with new technological processes;

      2) location of production lines, general development plans of urban and rural settlements’ construction, resort zones, feasibility studies, construction and reconstruction of objects for industrial and civil purpose;

      3) documents about healthcare and epidemiological situation of a land plot, planned for construction or an object, that is subject to reconstruction and changing of its functional profile (purpose);

      4) feasibility studies, projects and other regulatory documentation on emission limits and maximum allowable discharge of harmful substances and physical agents into environment, the zones of healthcare protection and healthcare protecting zones, geological researches, technology;

      5) draft regulations on raw materials, food, goods, products, substances, machinery, equipment, construction materials, as well as the modes of training, education, physical development, labor, housing, recreation, food, water supply, medical care of various groups the population;

      6) the conditions of production, transportation, storage, use and sale of raw materials, food, potable water, construction materials, consumer goods, toxic, radioactive and biological agents, as well as conduction of works and provision of services;

      7) the conditions of training, education, physical development, labor, housing, recreation, nutrition, water supply and medical treatment of different groups of population;

      8) the documents, describing the healthcare-epidemiological situation and the health status of the population, data on infectious and parasitic, occupational diseases and about poisonings;

      9) materials on chemical, biological, toxicological, radiological impact on soil, water and air;

      10) new products, technologies and equipment;

      11) the designed, constructed and commissioned objects of industrial and civil purpose, industrial products and transport, and other objects that are potentially dangerous and (or) important for public health;

      12) food products, materials and articles, contacting with food products that are not subject to mandatory conformity;

      13) academic workload and the mode of employment in educational institutions;

      14) children's products and nutritional supplements;

      15) development plans for settlements’ construction, location, construction and reconstruction of industrial and civil objects, buffer zones, conditions of water use and wastewater, recycling and disposal of toxic, radioactive and other hazardous substances, standards and regulations for new types of raw materials, equipment, processes of food production, food stock, industrial output, construction materials, ionizing radiation sources, chemicals and chemical products, biological, medicinal drugs, disinfectants, disinfestation and deratization devices, medical immunobiological drugs, packing, packaging and polymeric materials, contacting with food raw materials, food and drinking water, perfumes, cosmetics and other consumer goods, equipment, instruments and working tools;

      16) the objects of economic and (or) other activities in the settlements, the size of their buffer zones.

      9. On the basis of healthcare-epidemiological expertise, a healthcare-epidemiologic conclusion shall be issued (the hygienic certificate, health certificate) - the document, certifying compliance (incompliance) with the normative legal acts in healthcare-epidemiological welfare and hygienic standards of design documentation, environmental factors, business and (or) other activities, products, works and services.

      10.

Is excluded by the Law of the Republic of Kazakhstan, dated on 15.07.2011 No 461-IV (shall be enforced from 30.01.2012).

      Footnote. Article 62, as amended by the Laws of the Republic of Kazakhstan dated on 30.06.2010 No 297-IV (shall be enforced from 01.07.2010); dated on 06.01.2011 No 378-IV (shall be enforced upon expiration often calendar days after its first official publication); dated on 15.07.2011 No 461-IV (shall be enforced from 30.01.2012); dated on 10.07.2012 No 36-V (shall be enforced upon expiration often calendar days after its first official publication.)

**Article 63. Expert examination of drugs, medical devices and medical equipment**

      1. Expert examination of drugs, medical devices and medical equipment - a research or testing of drugs, medical devices and medical equipment for their safety, effectiveness and quality through physical, chemical, biological, pre-clinical (non-clinical) research, clinical studies, determination of bioequivalence as well as the study of documents of the registration dossier, regulations on standardization, submitted for registration of drug, medical device and medical equipment in the manner, defined by the authorized body.

      2. Expert examination of drugs, medical devices and medical equipment shall be referred to the state monopoly and shall be performed by a republican state enterprise on the basis of economic control rights, which is the state expert organization for circulation of drugs, medical devices and medical equipment.

      Prices of goods (works, services), produced and (or) sold by a state monopoly subject are specified by the Government of the Republic of Kazakhstan.

      Footnote. Article 63, as amended by the Law of the Republic of Kazakhstan, dated on 10.07.2012 No 34-V (shall be enforced from the date of its first official publication).

**Article 63-1. Evaluation of safety and quality of drugs and medical devices, registered in the Republic of Kazakhstan**

      1. Evaluation of safety and quality of drugs and medical devices, registered in the Republic of Kazakhstan shall be performed to reveal compliance of safety and quality of drugs, medical devices with the registration dossier, regulations on standardization, on the basis of which they were registered in the Republic of Kazakhstan.

      2. Evaluation of safety and quality of drugs, medical devices, registered in the Republic of Kazakhstan shall be referred to a state monopoly, and shall be performed by a republican state enterprise on the basis of economic control rights, which is the state expert organization for drugs, medical devices and medical equipment, that has testing laboratories, accredited in accordance with the legislature of the Republic of Kazakhstan.

      Prices of goods (works, services), produced and (or) sold by a state monopoly subject shall be established by the Government of the Republic of Kazakhstan.

      Footnote. Chapter 12 as amended by adding Article 63-1 in accordance with the Law of the Republic of Kazakhstan, dated on 10.07.2012 No 34-V (shall be enforced from the date of its first official publication).

**Article 64. Scientific and medical expert examination**

      1. The objects of scientific and medical expert examination shall be:

      1) the draft programs of basic and aplied scientific researches;

      2) republican target scientific and medical programs;

      3) the results of the completed scientific and medical programs;

      4) scientific papers, nominated for the state awards of the Republic of Kazakhstan;

      5) scientific and medical developments, planned for practical application in healthcare.

      2. The order of scientific and medical expert examination shall be defined by the authorized body.

 **SECTION 4. PHARMACEUTICAL ACTIVITIES AND CIRCULATION OF MEDICATIONS, MEDICAL SUPPLIES AND MEDICAL EQUIPMENT**

 **Chapter 13. PHARMACEUTICAL ACTIVITY**

**Article 65. The system of circulation of medications, medical devices and medical equipment**

      A single system of circulation of medications, medical devices and medical equipment shall include:

      1) a state body for circulation of medications, medical devices and medical equipment;

      2) a state expert organization for circulation of medications, medical devices and medical equipment and its territorial subdivisions.

**Article 66. Types of pharmaceutical activity**

      1. Pharmaceutical activities shall include professional activities of individuals with higher or vocational secondary pharmaceutical education, as well as the legal entities, involved in healthcare.

      2. Pharmaceutical activity shall include the following types:

      1) production of drugs;

      2) production of medical supplies;

      3) production of medical equipment;

      4) manufacturing of drugs;

      5) manufacturing of medical devices;

      6) wholesale trade of medications;

      7) wholesale trade of medical products;

      8) wholesale trade of medical equipment;

      9) retail sale of medications;

      10) retail sale of medical products;

      11) retail sale of medical equipment.

**Article 67. Production of medications, medical devices and medical equipment**

      1. Production of medications, medical devices and medical equipment - a pharmaceutical activity, including the range of all works, required for mass production of medications, medical devices and medical equipment, related to the purchase of raw materials and semi-products, technological process, including fulfillment of one of its phases, storage, sale of the produced output, as well as all kinds of the associated control.

      2. Manufacturing of medications, medical devices and medical equipment shall be performed in accordance with the production rules and normative documents on standardization by the subjects, involved in circulation of drugs, medical devices and medical equipment and that have received a license for production of medications, medical devices and medical equipment.

      3. Production rules and quality control, as well as testing of stability and setting of a shelf-life and re-control of medications, medical devices and medical equipment shall be defined by the Government of the Republic of Kazakhstan.

      4. Manufacture drugs, medical devices and medical equipment shall be prohibited if they:

      1) have not passed the state registration in the Republic of Kazakhstan, except for the drugs, medical devices and medical equipment, designed for expert examinations in their state registration, installation and launch of equipment and technological processes, as well as drug substances, produced under the Good Manufacturing practice;

      2) without a license for production of medications, medical devices and medical equipment;

      3) in violation of production Rules and quality control of drugs, medical devices and medical equipment.

      5. The produced and imported medications:

      1) shall not contain dyes and auxiliary agents, which are prohibited for use in the Republic of Kazakhstan by the authorized body;

      2) shall be controlled in accordance with the regulatory and technical document for control over the quality and safety of drugs, developed in compliance with the Rules of drawing up, approval and examination of normative and technical document for control over the quality and safety of drugs, established by the authorized body.

      6. Production and sale of patented medications, medical devices and medical equipment shall be performed in accordance with the legislation of the Republic of Kazakhstan in intellectual property area.

      7. Production of medical devices and medical equipment, designed for diagnostics or treatment must ensure their safety, provide their use in accordance with functional purposes and eliminate the risk of errors when interpreting the results of diagnostics or treatment.

      Footnote. Article 67, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 68. Production of pharmaceuticals and medical devices**

      Pharmaceuticals and medical products shall be produced by the subjects, involved in circulation of drugs, medical devices, properly licensed for manufacturing of pharmaceuticals and medical devices in accordance with the rules, approved by the authorized body. The manufactured drugs shall be subject to intrapharmacy control in the manner, approved by the Government of the Republic of Kazakhstan.

      Footnote. Article 68, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 69. Wholesale and retail trade of pharmaceuticals, medical devices and medical equipment**

      1. Wholesale trade of drugs, medical devices and medical equipment shall be performed by the subjects involved in circulation of drugs, medical devices and medical equipment, and obtained the appropriate license for wholesale trade in pharmacy depots or have notified about working in the order, defined by the Law of the Republic of Kazakhstan "On administrative procedures".

      2. Retail trade of pharmaceuticals, medical devices and medical equipment shall be carried out by the subjects that are involved in circulation of drugs, medical devices and medical equipment, and have obtained the appropriate license for retail trade in pharmacies, drugstores, mobile pharmacy stations, or have notified on beginning of activity in the order, established by the Law of the Republic of Kazakhstan "On administrative procedures."

      3. Wholesale and retail trade of pharmaceuticals, medical devices and medical equipment shall be performed in the order, defined by the Government of the Republic of Kazakhstan.

      4. Wholesale and retail trade of drugs, medical devices and medical equipment shall be prohibited:

      1) if they have not passed the state registration in the Republic of Kazakhstan, except for the drug substances, produced under the Good Manufacturing Practice;

      2) if their quality has not been confirmed by a conclusion on safety and quality in accordance with the order, defined by the legislature of the Republic of Kazakhstan;

      3) if they do not meet the requirements of the legislation of the Republic of Kazakhstan;

      4) if they are expired;

      5) to the healthcare workers in healthcare organizations, except for the cases, provided in paragraph 6 of this Article;

      6) through temporary storage of medications, medical devices and medical equipment.

      5. Sale of OTC drugs, requiring prescription shall be prohibited.

      The rules of referring drugs to prescription requiring or OTC medications shall be set by the Government of the Republic of Kazakhstan.

      6. In remote rural districts, where there are no pharmacies, the medications, medical devices may be sold by individuals and legal entities through pharmacies in healthcare organizations, providing primary health care, consultative and diagnostic care, and mobile pharmacies.

      In this case, in the absence of pharmaceutical specialists, the quality safety, the safety and efficacy of drugs, medical devices shall be ensured by the medical professionals, certified in the manner, defined by the authorized body.

      7. The medications, medical supplies and medical equipment, imported and produced in the territory of the Republic of Kazakhstan, shall be used, handled and operated on the territory of the Republic of Kazakhstan without restrictions before the expiration of the registration certificate.

      Footnote. Article 69, as amended by the Laws of the Republic of Kazakhstan dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011); dated on 10.07.2012 No 34-V (shall be enforced from the date of its first official publication); dated on 10.07.2012 No 36-V (shall be enforced upon expiration often calendar days after its first official publication.)

 **Chapter 14. CIRCULATION OF DRUGS, MEDICAL DEVICES AND MEDICAL EQUIPMENT**

**Article 70. Development of drugs, medical devices and medical equipment**

      1. The goal of developing drugs, medical devices and medical equipment shall be to create safe, effective and qualitative drugs, medical devices and medical equipment.

      2. The rights of a developer of drug products, medical devices and medical equipment shall be protected by the legislation of the Republic of Kazakhstan on intellectual property.

      3. The developer of drugs, medical devices and medical equipment must comply with the national standards’ requirements.

      4. The order of approving the names of the original drug shall be defined by the authorized body.

      Footnote. Article 70, as amended by the Law of the Republic of Kazakhstan, dated on 10.07.2012 No 31-V (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 71. The state registration, re-registration and amendments to the registration dossier of drugs, medical devices and medical equipment**

      1. The state registration of drugs, medical devices and medical equipment - the procedure, aimed at estimation of lawfulness of presence at the pharmaceutical market, safety, efficacy and quality of drugs, medical devices and medical equipment, and introduction of the drug, medical devices and medical equipment to the State register of drugs, medical devices and medical equipment for a specified period of time, performed in the order, defined by the authorized body.

      2. The state re-registration of drugs, medical devices and medical equipment - the extension of validity of the state registration for a specified period of time, accompanied by the issuance of a new registration certificate under the same registration number as well as the introduction of the corresponding entry in the State Register of drugs, medical devices and medical equipment, performed in the order, established by the authorized body.

      3. Amendments to the registration dossier - the changes, made by an applicant to the registration dossier during the currency of the registration certificate, that do not affect safety, efficacy and quality of drugs, medical devices and medical equipment, and are subject to examination in the order, established by the authorized body.

      4. The drugs, medical devices and medical equipment, produced in the Republic of Kazakhstan, as well as those, imported to its territory, shall be subject to the state registration and re-registration, including:

      1) the drugs under the trade-names indicating drug formulation, dosage, and packaging;

      2) bulk drug products, imported into the Republic of Kazakhstan;

      3) new combinations of the drugs, previously registered in the Republic of Kazakhstan, with an indication of drug formulation, dosage and packaging;

      4) the drugs, previously registered in the Republic of Kazakhstan, but produced by other manufactures in other drugs formulations with new dosage forms, new packaging, a different composition of excipients, another name;

      5) medical products and medical equipment, taking into account their classification according to the degree of potential risk for medical applications;

      6) medical devices, designed for in vitro diagnostics testing of a human body, except for the diagnostic reagents, not related to the medical immunotherapeutic agents, as well as contact lenses for vision correction.

      5. Trade name of a drug - the name under which the drug shall be registered.

      6. Bio similar - the second-entry biopharmaceutical, claimed to be similar in quality, safety and efficacy to the previously registered, innovative biological drug and having a similar international non-proprietary name.

      7. The drugs of biological origin - the pharmaceuticals, containing biological proteins (hormones, cytokines, blood clotting factors, including low molecular weight heparin, insulin, monoclonal antibodies, enzymes, colony stimulating factors, drugs developed on the basis of tissue cells, obtained by genetic engineering and hybridoma technology) and biosimilars.

      8. The drugs, medical devices and medical equipment, registered in the country of origin shall be subject to the state registration in the Republic of Kazakhstan.

      9. Upon the decision of the authorized body, the drugs, medical supplies and medical equipment may be registered under the accelerated procedure of the state registration, re-registration. The order of the accelerated procedure of the state registration, re-registration of drugs, medical devices and medical equipment shall be defined by the authorized body.

      10. After termination of the state registration, the drugs, medical devices and medical equipment shall be subject to re-registration in the Republic of Kazakhstan in the order, defined by the authorized body.

      11. An obligatory condition of the state registration, re-registration, amendments to the registration dossier - an examination of the drug, medical device and medical equipment.

      In accordance with the procedure, approved by the authorized body, the examination shall be performed by the state expert organization in circulation of drugs, medical devices and medical equipment.

      Assessment of production conditions and quality assurance system shall be performed via visiting of a manufacturer at the expense of an applicant for the state registration of drugs, medical devices and medical equipment in the manner, specified by the authorized body.

      The expenses, associated with the examination of the drug, medical device and medical technology for their registration and re-registration, shall be covered by the applicants.

      12. The drugs, produced in pharmacies, medical products, made in the stores of medical technology and medical products, medical optics products, manufactured in optical stores, as well as drug substances, produced under the Good Manufacturing Practices shall not be subject to the state registration.

      13. An application for the state registration and re-registration, amendments to the registration dossier of drugs, medical devices and medical equipment, and (or) their expendable materials shall be submitted in a written form by a developer or a manufacturer of the drug, medical device and medical technology, responsible for the quality of the claimed products at all stages of their promotion, or by their representatives.

      The application shall be attached with the registration dossier, containing the documents, the list of which shall be defined by the authorized body.

      Accounting and systematization of documents, submitted by the applicant for the state registration, re-registration and amendments to the registration dossier of drugs, medical supplies and medical equipment, subjected to the agreement or approval, shall be performed in the order, defined by the authorized body.

      14. Fee shall be charged for the state registration, re-registration and issuance of a duplicate of a registration certificate of drug products, medical devices and medical equipment in the order, defined by the tax legislature of the Republic of Kazakhstan.

      15. The applicant shall receive denial of the state registration and re-registration and of amendments to the registration dossier of drugs, medical devices and medical equipment in case of their non-compliance with the declared parameters of quality, safety and efficacy in the order, specified by the authorized body.

      16. Upon the results of the state registration and re-registration of drug, medical devices and medical equipment, a state registration certificate shall be issued and its sample shall be specified by the authorized body.

      17. A decision on the state registration of drugs, medical devices and medical equipment may be revoked in the order, defined by the authorized body.

      18. During the validity period of the registration certificate, the manufacturer shall be responsible for the quality of the registered drugs, medical devices and medical equipment, available at the market of the Republic of Kazakhstan, that must comply with the samples, submitted for the state registration, re-registration and characteristics, specified in the registration dossier and be attached with the documents, containing information for a consumer, approved by the authorized body.

      Footnote. Article 71, as amended by the Law of the Republic of Kazakhstan; dated on 10.07.2012 No 34-V (shall be enforced from the date of its first official publication).

**Article 72. Pre-clinical (non-clinical) studies of biologically active substances**

      1. The purpose of pre-clinical (non-clinical) studies of biologically active substances is to receive scientific assessment and evidence of pharmacological activity and safety of biologically active substances.

      2. A decision on making pre-clinical (non-clinical) studies of biologically active substances shall be taken by the authorized body.

      3. Pre-clinical (non-clinical) studies shall be carried out in the order, defined by the authorized body.

**Article 73. Technical testing of medical devices and medical equipment**

      1. The purpose of technical testing of medical devices and medical equipment is to harmonize technical characteristics of medical devices and medical equipment with the national standards.

      2. A decision to conduct technical testing of medical devices and medical equipment shall be taken by the authorized body for technical regulation.

      Footnote. Article 73, as amended by the Law of the Republic of Kazakhstan, dated on 10.07.2012 No 31-V (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 74. Clinical studies and (or) testing of pharmacological and drug products, medical devices and medical equipment**

      1. Clinical studies and (or) testing of pharmacological and drug products, medical devices and medical equipment shall be performed with participation of a person as a subject for revealing or confirmation of clinical, pharmacological and (or) the pharmaco-dynamic effects of the tested medication, and (or) disclosure of adverse reactions and (or) in order to investigate absorption, distribution, biotransformation and excretion for assessment of its safety and efficacy.

      2. Clinical studies and (or) testing of pharmacological and drug products, medical devices and medical equipment are performed in the order, defined by the authorized body.

**Article 75. Labeling of drug product, medical device and medical equipment**

      1. The drugs should come into circulation with the labeling, printed on the consumer packaging (primary and secondary) with a well-read typeface in the State and Russian languages, and meet the requirements of the order, established by the Government of the Republic of Kazakhstan.

      2. Medical products and medical equipment shall come into circulation with the labeling, printed on the medical devices and medical equipment, and (or) on the consumer packaging in accordance with the order, established by the Government of the Republic of Kazakhstan.

      3. It shall be allowed to use stickers during importation of the limited number of expensive, rarely used, and orphan drugs.

      Applying of stickers on a consumer package shall be performed in the order, defined by the authorized body.

      Footnote. Article 75, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 76. Purchase of drugs, intended for the guaranteed volume of free medical assistance**

      1. The drugs, intended for the guaranteed volume of free medical care, shall be acquired under the international nonproprietary names. In case of purchase of a multi-component drug its composition shall be specified.

      2. For efficient and effective use of budget funds, allocated for purchase of drugs for the guaranteed volume of free medical care, the drugs shall be purchased at the prices not exceeding the costs, established by the authorized body.

**Article 77. A single distributor for procurement and provision of drugs, medical products**

      1. A single distributor for procurement and provision of medications, medical supplies shall be defined by the Government of the Republic of Kazakhstan.

      The main activity of a single distributor for procurement and provision of medications, medical products is to choose suppliers and conclude supply contracts, provide customers with drugs, medical products in accordance with the List of drugs, medical devices within the guaranteed volume of free medical care, defined by the authorized body, and storage and delivery of medications, medical devices by the customer.

      2. The rules for organization and procurement of drugs, medical devices shall be specified by the Government of the Republic of Kazakhstan.

      3. The main criterion for selecting a single distributor for procurement and provision of drugs, medical supplies as a potential supplier shall be the presence of the manufacturer status or an official representative of the manufacturer of the drug, medical device.

      4. The principles of procurement of drugs, medical devices shall be:

      1) optimal and effective use of money for procurements;

      2) provision of equal opportunities to the potential suppliers to participate in the procurement procedure;

      3) fair competition among the potential suppliers;

      4) openness and transparency of the procurement process;

      5) support for domestic producers.

      5. A single distributor for procurement and provision of medications, medical supplies shall be liable for failure and (or) improper performance of their duties in accordance with the Laws of the Republic of Kazakhstan.

**Article 78. Storage and transportation of drugs, medical devices and medical equipment**

      1. Drugs, medical devices and medical equipment shall be stored and transported under the conditions, providing their safety, efficacy and quality, in accordance with the regulations, adopted by the Government of the Republic of Kazakhstan.

      A temporary warehouse of drugs, medical devices and medical equipment must have premises, areas, special equipment, furniture, equipment, firefighting equipment, devices, providing compliance of drugs, medical devices and medical equipment with the storage requirements, defined by the technical rules and standardization regulations, as well as the resolution of the authorized body.

      2. It shall be prohibited to extend the shelf-life of drugs, medical devices.

      Footnote. Article 78, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced 13.10.2011).

**Article 79. Destruction of drugs, medical supplies and medical equipment**

      Drugs, medical devices and medical equipment that are useless, counterfeit, expired, and others, that do not meet the requirements of the legislation of the Republic of Kazakhstan, shall be considered unfit for sale and medical use and must be destroyed by the subjects, involved in circulation of drugs, medical devices and medical equipment, disposed by them, in the order, established by the Government of the Republic of Kazakhstan.

      Footnote. Article 79, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 80. The order of importation of drugs, medical devices and medical equipment**

      1. Importation of drugs, medical devices and medical equipment to the territory of the Republic of Kazakhstan shall be performed in the order, established by the Government of the Republic of Kazakhstan, in accordance with the legislation of the Customs Union and (or) the Republic of Kazakhstan.

      2. Import of drugs, medical devices and medical equipment into the territory of the Republic of Kazakhstan shall not be permitted if the medicinal products have not passed the state registration in the Republic of Kazakhstan, except for the drug substances, manufactured under the Good Manufacturing Practice, and the cases, referred to in paragraph 3 of this Article, Article 80-2 of this Code.

      3. Import of drugs, medical devices and medical equipment into the territory of the Republic of Kazakhstan, not registered in the Republic of Kazakhstan shall be allowed under a resolution (permission), issued by the authorized body if they are intended for:

      1) organization of clinical research;

      2). expertise of drugs;

      3). the state registration of drugs, medical devices and medical equipment;

      4). medical care for a particular patient for life saving, or medical care for a particular group of patients with rare and (or) the most severe disease;

      5). organization of exhibitions without the right for their further distribution;

      6). prevention and (or) elimination of emergency situations;

      7) equipment of healthcare organizations with the unique medical technology, registered in the Republic of Kazakhstan, as well as the equipment of the medical purpose, related and designed for complement of the unique medical devices;

      8). introduction of innovative medical technologies;

      4. Import of drugs, medical devices and medical equipment shall be prohibited into the territory of the Republic of Kazakhstan as humanitarian aid, that have not passed the state registration, except for the specific cases, defined by the Government of the Republic of Kazakhstan.

      Drugs, medical devices and medical equipment (including the unregistered), intended for the humanitarian aid and assistance in emergency situations, shall be imported to the Republic of Kazakhstan under a resolution (permission), issued in the order, specified by the Government of the Republic of Kazakhstan.

      5. The drugs, medical devices and medical equipment, imported into the territory of the Republic of Kazakhstan, not complying with the legislation of the Republic of Kazakhstan on healthcare, shall be confiscated and destroyed.

      Footnote: Article 80 is in the wording of the Law of the Republic of Kazakhstan dated on 21.06.2013 No. 107-V (shall be enforced upon expiration of thirty calendar days after its first official publication).

**Article 80-1. The persons, entitled to import drugs, medical devices and medical equipment to the Republic of Kazakhstan**

      In accordance with the order, specified by the Government of the Republic of Kazakhstan, the import of drugs, medical devices and medical equipment to the Republic of Kazakhstan may be performed:

      1) by producer-organizations, licensed to manufacture drugs, medical devices and medical equipment;

      2) by individuals or legal entities, licensed for wholesale trade of drugs or included in the register of healthcare subjects, engaged in wholesale trade of medical devices and medical equipment, according to the notice of the commencement of business;

      3) by research organizations, laboratories for development and state registration of drugs, medical devices and medical equipment in accordance with this Code;

      4) by foreign manufactures of drugs, medical devices and medical equipment, their authorized representatives (affiliates) or their authorized individuals and legal entities for examination in the state registration, clinical testing, and (or) research, and for participation in exhibitions of manufacturers of drugs, medical devices and medical equipment in the Republic of Kazakhstan;

      5) by healthcare organizations for providing medical activities.

      Footnote. The Code shall be supplemented by Article 80-1 in accordance with the Law of the Republic of Kazakhstan dated on 21.06.2013 No. 107-V (shall be enforced upon expiration of thirty calendar days after its first official publication).

**Article 80-2. Importation of drugs, medical devices and medical equipment for personal use and other non-commercial purposes**

      1. Drugs, medical devices and medical equipment shall be imported with a permission of the authorized body if they are intended for:

      1). personal use of the individuals, representatives of the diplomatic missions and international organizations;

      2). treatment of passengers and crew of vehicles, train staff and drivers of vehicles, that arrived to the customs territory of the Customs Union;

      3). treatment of the participants of cultural and sports events, and the members of international expeditions;

      2. In the cases, specified by paragraph 1 of this Article, importation of drugs, medical devices and medical equipment, not registered in the Republic of Kazakhstan, shall be permitted.

      Footnote. The Code shall be supplemented by Article 80-2 in accordance with the Law of the Republic of Kazakhstan dated on 21.06.2013 No. 107-V (shall be enforced upon expiration of thirty calendar days after its first official publication).

**Article 80-3. Interaction of the authorized body and the authorized body for customs affairs of the Republic of Kazakhstan**

      1. When moving across the customs border of the Customs Union, coinciding with the state border of the Republic of Kazakhstan of drugs, medical devices and medical equipment to the customs authorities of the Republic of Kazakhstan, the information on the state registration of each of the imported drugs, medical supplies and medical equipment, indicating the date and number of registration, shall be submitted, confirmed by the authorized body, except for the cases, specified by paragraphs 3 and 4 of Article 80, Article 80-2 of this Code.

      2. The authorized body on customs affairs of the Republic of Kazakhstan shall provide information to the authorized body on importation of pharmaceuticals, medical devices and medical equipment to the territory of the Republic of Kazakhstan through the customs border of the Customs Union, coinciding with the state border of the Republic of Kazakhstan and export from the territory of the Republic of Kazakhstan through the customs border of the Customs Union, coinciding with the state border of the Republic of Kazakhstan of the pharmaceuticals, medical devices and medical equipment.

      Footnote. The Code is supplemented by Article 80-3 in accordance with the Law of the Republic of Kazakhstan dated on 21.06.2013 No. 107-V (shall be enforced upon expiration of thirty calendar days after its first official publication).

**Article 81. The order of export of drugs, medical devices and medical equipment**

      1. Export of drugs, medical devices and medical equipment from the territory of the Republic of Kazakhstan shall be performed in the order, approved by the Government of the Republic of Kazakhstan.

      2. Drugs, medical devices and medical equipment may be exported from the territory of the Republic of Kazakhstan without the approval of the authorized body:

      1) for personal use in the amount required for a course of treatment, by the individuals, leaving the territory of the Republic of Kazakhstan;

      2) in the first-aid kits of a vehicle, leaving the territory of the Republic of Kazakhstan, for treatment of passengers.

      3. Export of drugs, medical devices and medical equipment from the territory of the Republic of Kazakhstan as part of material and technical devices of medical and rescue organizations and groups, leaving the territory of the Republic of Kazakhstan to liquidate emergency situations, shall be performed in the order, established by the Government of the Republic of Kazakhstan.

      Footnote. Article 81, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

 **Chapter 15. GENERAL SAFETY REQUIREMENTS TO DRUGS, MEDICAL DEVICES AND MEDICAL EQUIPMENT**

**Article 82. Installation, repair, technical and metrological maintenance of medical devices and medical equipment**

      1. Installation, repair, technical and metrological maintenance of medical equipment and in some cases medical products shall be performed by individuals or legal entities, entitled to conduct these works in accordance with the legislation of the Republic of Kazakhstan.

      2. The level of security of medical devices and medical equipment after the repair should not be below the level of safety, established by the technical certificate of medical devices and medical equipment.

      3. Metrological provision of medical measurement devices, applied in healthcare organizations shall be regulated in accordance with legislation of the Republic of Kazakhstan on technical regulation.

      4. Medical technology, which is a means of measurement, shall be registered in the Registrar of the state traceability system of the Republic of Kazakhstan and shall be allowed for use in accordance with the legislation of the Republic of Kazakhstan on uniformity of measurements.

      The list of medical equipment, being a means of measurement, shall be approved by the authorized body in coordination with the authorized body in the scope of technical regulation.

**Article 83. Safety classification and safety reclassification of medical devices and medical equipment, depending on the potential risk degree**

      1. Medical devices and medical equipment, used in the Republic of Kazakhstan, shall be divided into the safety classes, depending on the potential risk degree of making harm to patients, staff, operating medical devices and medical equipment, and other persons.

      Each safety class shall include the groups and types of medical products and medical equipment, meeting certain technical regulations. Medical devices and medical equipment may not simultaneously belong to several safety classes.

      2. The rules of safety classification of medical devices and medical technology shall be approved by the authorized body in coordination with the competent authorized body for technical regulation.

      3. Classification principles of medical devices and medical equipment shall take into account:

      1) the duration of use;

      2) invasiveness;

      3) presence of contact with an organism or interaction with it;

      4) a mode of administration into the body;

      5) application for the vital organs;

      6) the use of energy sources.

      4. Affiliation to the safety classes of medical products, medical devices and medical equipment shall be defined by the authorized body during their state registration.

      5. A manufacturer shall be entitled to conduct reclassification, at least in two years after the state registration if there are grounds for the safety re-classification of the registered medical products, medical devices and medical equipment, in the order, established by legislation of the Republic of Kazakhstan in healthcare.

      6. The authorized body may introduce changes in classification, taking into account the principles, characteristics, medical techniques, used for the work of medical devices and medical equipment.

**Article 84. Prohibition, suspension or withdrawal of drugs, medical devices and medical equipment**

      1. The authorized body may prohibit or suspend the use, sale or production of drugs, medical devices and medical equipment, as well as to make a decision to withdraw them in the following cases:

      1) non-compliance of drugs, medical devices and medical equipment with the technical regulations and standardization documents;

      2) revealing of adverse drug reactions, dangerous to human health, that are not specified in the drug usage leaflet;

      3) detection of defects in design, mode of operation, production performance, affecting their safety when applying medical devices or medical equipment;

      4) violation of the approved process of production of drugs, medical devices and medical equipment, affecting their quality, safety and efficiency;

      5) the available data on harming the health of a patient or a consumer, caused by the use of drugs, medical devices and medical equipment;

      6) obtaining the data on insufficiency of scientific and technological level of production technology and quality control, reducing the safety level of drugs, medical devices and medical equipment.

      2. The order of prohibition, suspension or withdrawal from circulation shall be established by the Government of the Republic of Kazakhstan.

      Footnote. Article 84, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced 13.10.2011).

**Article 85. Monitoring of drug side-effects**

      1. Monitoring of drug side effects shall be performed in medical and pharmaceutical organizations in the order, approved by the authorized body.

      2. In a written form, the healthcare subjects shall have to inform the authorized body on the facts of special interaction of a drug with other drugs and side effects, including those, not listed in the drug use instructions.

**Article 86. Information on new drugs, medical devices and medical equipment**

      Information on new drugs, medical devices and medical equipment, approved for use in the Republic of Kazakhstan, on the drugs, that have not passed the state registration and do not meet the requirements of the legislation of the Republic of Kazakhstan on healthcare, on revocation of the decision on the state registration, as well as on doctor's prescription drugs shall be provided in the specialized printed media, designed for medical and pharmaceutical workers.

 **SECTION 5. PROTECTION OF PUBLIC HEALTH**

 **Chapter 16. RIGHTS AND RESPONSIBILITIES IN HEALTHCARE AND WARRANTIES OF THEIR SECURITY**

**Article 87. Guarantees of rights security in healthcare**

      The state shall guarantee the citizens of the Republic of Kazakhstan:

      1) the right for health care;

      2) provision of the guaranteed volume of free medical care;

      3) equal access to medical care;

      4) quality of health care;

      5) the availability, quality, effectiveness and safety of drugs;

      6) taking of measures to prevent diseases, promote healthy lifestyles and healthy eating;

      7) privacy, preservation of information, which is a part of doctor-patient confidentiality;

      8) freedom of reproductive choice, protection of reproductive health and observance of reproductive rights;

      9) healthcare-epidemiological, environmental welfare and radiation safety.

**Article 88. The citizens’ rights**

      1. Citizens of the Republic of Kazakhstan shall have the right to:

      1) the guaranteed volume of free medical care in accordance with the list, approved by the Government of the Republic of Kazakhstan;

      2) the drugs and medical devices in the frames of the guaranteed volume of free medical care, including provision of the certain categories of people with certain diseases (statuses) with free or the reduced-price drugs and specialized medical products on an outpatient basis in accordance with the list, approved by the authorized body;

      3) free choice of a medical organization, qualitative and timely medical assistance;

      4) additional medical services in addition to the guaranteed volume of free medical care at the expense of own funds, the organizations’ funds, the system of voluntary insurance and other not-prohibited sources;

      5) receive medical care abroad at the expense of budget funds, when clinically indicated, in the order, defined by the Government of the Republic of Kazakhstan;

      6) compensation for the harm, caused to the health by wrong assignment and use of drugs, medical devices and medical equipment by the health workers;

      7) certification of temporary disability with the issuance of a temporary disability leave or a temporary disability certificate;

      8) receive reliable information on prevention, diagnosis, treatment and rehabilitation, clinical studies, factors, affecting health, including the environment, working conditions, living and recreation, healthy food and food safety, including the conclusions of healthcare-epidemiological expertise from the state bodies, organizations and attending physician within their competence;

      9) receive information on safety, efficacy and quality of drugs sold, medical devices and medical equipment from the state bodies, independent expert organizations and subjects, involved in circulation of drugs, medical devices and medical equipment;

      10) appeal the actions (or inaction) of medical and pharmaceutical personnel in healthcare organization, higher authority and (or) in a judicial procedure;

      11) an application for attracting independent experts in case of disagreement with the findings of the state medical expertise.

      2. A woman has the right to resolve an issue on motherhood and the free choice of modern methods of unwanted pregnancy prevention for family planning and protection of her health.

      The right of citizens to protection of maternity shall be provided by:

      1) a medical examination within the frames of the guaranteed volume of free medical care, dynamic screening and health improvement of women of reproductive age;

      2) medical treatment of major diseases, directly affecting women's reproductive health and child’s health, when being hospitalized for care for a sick child.

      Working hours, maternity leave and working conditions of pregnant women and nursing mothers shall be established in accordance with the labor legislation of the Republic of Kazakhstan.

      3. People with gender identity disorders, except for those with mental disorders (diseases) shall have the right to change their sex.

     The rules of medical examination and sex change operations for persons with gender identity disorders shall be established by the Government of the Republic of Kazakhstan.

      4. The citizens, whose freedom is limited, and those, serving a sentence in prison, placed in special institutions, shall receive the medical care in the order, defined by the Government of the Republic of Kazakhstan. These persons shall enjoy all the above rights of the citizens of the Republic of Kazakhstan when receiving medical care.

      5. Foreigners and stateless persons, residing in the territory of the Republic of Kazakhstan, shall have the right to receive the guaranteed volume of free medical care in acute diseases, posing threat to others, in compliance with the list, specified by the Government of the Republic of Kazakhstan, unless otherwise stipulated by the international treaties, ratified by the Republic of Kazakhstan.

      6. Citizens shall have the right to receive e-government services in healthcare area through a web portal of "electronic government" in the order, defined by the Government of the Republic of Kazakhstan.

      Footnote. Article 88, as amended by the Laws of the Republic of Kazakhstan dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011); dated on 08.01.2013 No 64-V (shall be enforced from 01.01.2013); dated on 15.04.2013 No 89-V (shall be enforced upon expiration of thirty calendar days after its first official publication).

**Article 89. Children's rights**

      1. Every child shall have the right to:

      1) use modern and effective healthcare services and devices for medical treatment and health rehabilitation;

      2) get education in healthcare protection;

      3) medical examinations and case follow-ups, treatment, drug supply and health improvement in the frames of the guaranteed volume of free medical care.

      2. When hospitalized the children:

      1) under three years old, and very sick older children, who, according to the doctors, need additional care, the mother (father) or any other person, taking care of the child, shall have the opportunity to be with him in the medical organization with the issuance of a temporary disability leave;

      2) a nursing mother with a child under one year of age shall be provided with free meals in a medical organization for the whole period of a child’s hospitalization.

      3. School-age children during their inpatient, rehabilitation treatment shall have the right for regular training in the hospital, rehabilitation centerand sanatorium.

      Patients of the children's inpatient departments and specialized children’s inpatient medical organizations shall have the necessary conditions for games, recreation and educational work.

      4. The children with disabilities, as well as HIV-infected, and AIDS patients shall have the right for a free medical and educational support in education and healthcare organizations, in accordance with the legislation of the Republic of Kazakhstan in healthcare.

      The HIV-infected children shall have a right to stay in orphanages and other medical and educational institutions for general purpose.

      5. The list of medical contraindications to place children in the orphanage and education organizations, organizations for orphans and children left without parental care shall be approved by the authorized body.

**Article 90. Duties of citizens, individual entrepreneurs and legal entities**

      1. Citizens shall be obliged to:

      1) preserve their health;

      2) observe the regime, acting in healthcare organizations;

      3) undergo preventive medical examinations in accordance with the legislature of the Republic of Kazakhstan in healthcare;

      4) observe the requirements of medical workers, bodies and healthcare organizations, related to the individual and public health;

      5) observe precautions to protect their own health and the health of others, to pass screening and treatment on demand of healthcare organizations, to inform medical staff about the disease in infectious diseases and the diseases, posing threat to others.

      In case of evasion from medical examination and treatment, the citizens, the patients with the diseases, dangerous to others, shall be subject to mandatory examination and treatment in accordance with this Code and other laws of the Republic of Kazakhstan.

      The grounds and procedure for sending the people, suffering from diseases dangerous to others, to mandatory treatment, shall be regulated by this Code;

      6) observe the legislation of the Republic of Kazakhstan in healthcare.

      2. Pregnant women up to twelve weeks of pregnancy shall have to start the medical records.

      3. Foreigners and stateless persons, residing in the territory of the Republic of Kazakhstan, shall have the same duties in healthcare area as the citizens of the Republic of Kazakhstan.

      4. In accordance with their activities, the individual entrepreneurs and legal entities shall:

      1) take healthcare-epidemiological (preventive) measures;

      2) meet the requirements of regulatory legal acts in healthcare and epidemiological welfare and hygienic standards, as well as the regulations and healthcare-epidemiological conclusions of officials, involved in the state healthcare and epidemiological supervision;

      3) ensure safety and quality of works performed, services and products in its production, transportation, storage and sale;

      4) conduct a production control in accordance with the legislation of the Republic of Kazakhstan;

      5) inform timely the state healthcare-epidemiological services on emergencies, suspension of productions, violations of technological processes, threatening the healthcare-epidemiological welfare of the population, in cases of mass and group infectious and parasitic, occupational diseases and poisoning;

      6) inform promptly the authorized body on the side-effects of drugs and medical devices in case of their detection;

      7) ensure hygienic training of employees, working in the service sector, which poses a threat to infect others with the infectious and parasitic diseases;       8) allow the officials of state healthcare-epidemiological services to conduct sampling of products, raw materials, goods, work environment for laboratory testing in accordance with their competence;

      9) not allow the persons without a medical examination certificate to work, as well as to suspend from work those with infectious diseases and carriers of infectious diseases, detected by public health organizations;

      10) not allow to sell goods, products, raw materials if they do not meet the requirements of normative legal acts in healthcare and epidemiological welfare of the population and health standards, as well as to make a decision on their use or disposal;

      11)

excluded by the Law of the Republic of Kazakhstan; dated on 15.07.2011 No 461-IV (shall be enforced from 30.01.2012).

      12) submit records and reporting documentation on healthcare and epidemiological welfare to the state healthcare-epidemiological services for review;

      13) suspend business and (or) any other activity in case if they pose threat to life or health of population;

      14) ensure unhindered access of officials, exercising the state healthcare-epidemiological supervision to the objects in order to verify their compliance with the regulations in healthcare and epidemiological safety and health standards;

      15) conduct disinfection, disinfestation and deratization activities upon epidemiological indications and regulations, and decrees of officials of healthcare-epidemiological services at their own expense.

      Footnote. Article 90, as amended by the Laws of the Republic of Kazakhstan dated on 06.01.2011 No 378-IV (shall be enforced upon expiration often calendar days after its first official publication); dated on 15.07.2011 No 461-IV (shall be enforced from 30.01.2012).

**Article 91. Patients’ rights**

      1. In addition to the rights, specified in Article 88 of this Code, a patient shall have the following rights:

      1) a decent treatment during diagnostics, medical treatment and care, respect for his cultural and personal values;

      2) a medical care in the order, determined solely on the basis of medical criteria, without the influence of any discriminatory factors;

      3) a choice, replacement of a physician or a medical organization;

      4) support of his family, relatives and friends, as well as the members of religious communities;

      5) relief of suffering to the extent that is provided by the current level of medical technologies;

      6) to receive an independent opinion on his health status and have a consultation;

      7) other rights, provided by the laws of the Republic of Kazakhstan.

      2. A patient shall have the right to be informed of his rights and responsibilities, the provided services, the cost of the paid medical services, as well as the order of their provision. Information on a patient's rights must be placed in billboards in medical organizations.

      When being hospitalized, a patient should be provided with the information about the names and professional status of those who shall provide medical services, as well as the internal rules of the medical organization.

      3. Medical assistance shall be provided after the oral or written voluntary consent of a patient.

      4. When a patient receives medical care, he shall have a right to be fully informed about his health status, including information about the risks and benefits of the proposed and alternative treatments, information about the possible consequences of refusing the treatment, information on diagnosis, prognosis and plan of remedial measures in an accessible form, as well as an explanation of his discharge from the hospital or transfer to another medical institution.

      5. A patient may appoint a person to whom the information on his health status should be provided. The patient's refusal from obtaining the information shall be made in a written form and included in the medical record.

      6. Information may be hidden from the patient in the cases where there are reasonable grounds to believe that the medical information shall not do good for him and cause serious harm to him. In this case, this information shall be reported to the spouse (wife) of the patient, his relatives or legal representatives.

      7. The patients receiving medical care in the clinical educational institutions in healthcare shall have the right to refuse to participate in the teaching process, as well as the presence of the third parties during therapeutic and diagnostic procedures.

      8. The patients’ rights shall be protected by the healthcare bodies, healthcare organizations, as well as public organizations within their jurisdiction.

      9. When receiving medical care a patient shall have a right to be fully informed about the prescribed drugs.

      10. Citizens, who are getting married, shall have a right to health and medical genetic examination.

**Article 92. Responsibilities of patients**

      1. In addition to the duties, specified in Article 90 of this Code, the patient shall:

      1) take measures to preserve and strengthen his health;

      2) communicate with health care workers respectfully;

      3) tell a doctor all the information, required for diagnosis and treatment, after giving a consent for medical intervention to comply strictly with all the requirements of a doctor;

      4) observe the internal rules and take good care of the property of the medical organization, to cooperate with the medical staff when obtaining medical care;

      5) inform health professionals about the changes in his health status during the diagnosis and treatment, as well as in the cases of diseases, dangerous to others, or their possibility on time;

      6) not commit acts, violating the rights of other patients;

      7) perform other duties, provided by the Laws of the Republic of Kazakhstan.

      2. Duties of the patients referred to in subparagraphs 2) - 4) of paragraph 1 of this Article shall be applied to the parents or other persons, directly involved in a hospital care for a sick child.

**Article 93. The right to refuse medical treatment**

      1. A patient or his legal representative shall have the right to refuse medical treatment, except for the cases, provided for in Article 94 of this Code.

      2. In case of refusal from medical care, form the patient or his legal representative shall be informed about the possible consequences in an easily-accessible.

      3. Refusal from medical treatment, providing of information about the possible consequences shall be recorded in medical records and signed by the patient or his legal representative, as well as by a medical worker.

      In case of refusal to sign by the patient or his legal representative the refusal from medical care, a relevant entry about this shall be made in the medical record and signed by a medical professional.

      4. Upon refusal of legal representatives of a minor or an incapacitated person from medical care, required to save the lives of these persons, a medical organization shall have the right to apply to the guardianship authority and (or) to the court to protect their interests.

**Article 94. Providing medical care without the consent of the citizens**

      1. Medical care without consent shall be provided to the persons:

      1) in shock, coma, not allowing them to express their will;

      2) suffering from diseases dangerous to others;

      3) severe mental disorders (diseases);

      4) mental disorders (diseases) and those, who committed socially dangerous act.

      2. The consent for medical care for minors and citizens, declared incompetent by a court shall be given by their legal representatives. In the absence of the legal representatives, a decision on medical assistance shall be taken by the concilium, and if it is impossible to gather a concilium - by a medical professional with the notification of the officials of the medical organization and legal representatives.

      3. Medical care without the consent of the citizens shall go on until elimination of grounds, provided for in paragraph 1 of this Article.

      Footnote. Article 3, as amended by the Law of the Republic of Kazakhstan dated on 29.12.2010 No 375-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 95. Medical secrecy**

      1. Information on seeking medical advice, the health status of a citizen, his diagnosis and other information, received during his examination and (or) treatment, shall be the medical secrecy.

      2. Disclosure of information, which is a part of a patient’s confidentiality shall not be allowed to the persons who have learnt it during training, professional performance, service and other obligations, except for the cases, defined by paragraphs 3 and 4 of this Article.

      3. With the consent of a patient or his legal representative, the information constituting a medical secret may be transferred to other individuals and (or) legal entities for the benefit of examination and treatment of the patient, for research, teaching process and for other purposes.

      4. Presentation of information, constituting a medical secret, without the consent of the patient or his legal representative shall be allowed in the following cases:

      1) for the purposes of examination and treatment of a citizen, unable to express his will because of his condition;

      2) the threat of diseases dissemination, posing threat to others;

      3) at the request of inquiry and preliminary investigation bodies, prosecutor, lawyer, and (or) a court in view of investigation or prosecution;

      4) when providing medical care to a minor or an incapable person to inform his legal representatives;

      5) if there are grounds to believe that the injury, caused to the citizen is a result of illegal acts.

      5. Without the permission of the patient, placement and use of personal data, related to his private life shall not be allowed for use in the automated databases.

      The automated databases, containing the personal information of individuals, may not be connected to the networks, linking them with other databases, without the permission of the individual (patients) when using their private information, concerning their private life.

      Footnote. Article 95 as amended by the Law of the Republic of Kazakhstan dated on 21.05.2013 No. 95-V (shall be enforced upon expiration of six months after its first official publication)

 **Chapter 17. PROTECTION OF REPRODUCTIVE RIGHTS**

**Article 96. The rights and duties of citizens in ??reproductive rights area**

      1. Citizens, shall have the right to:

      1) free reproductive choice;

      2) receive services for protection of reproductive health and family planning;

      3) receive reliable and complete information about their reproductive health status;

      4) treatment of infertility, including the use of modern auxiliary reproductive techniques and technologies, allowed in the Republic of Kazakhstan;

      5) donation of germ cells;

      6) use and free choice of contraceptive methods;

      7) surgical sterilization;

      8) abortion;

      9) protection of their reproductive rights;

      10) take a free decision on the number of their children and time of their birth within wedlock or out of it, the periods between their birth, necessary to reserve mother’s and child’s health;

      11) storage of germ cells.

      2. The minors shall have the right to protection of reproductive health, and for moral and sexual education.

      3. The citizens shall be obliged to respect the rights, freedoms and legitimate interests of other citizens when exercising their reproductive rights.

**Article 97. Protection of women’s health during pregnancy, delivery and postpartum**

      1. A woman shall have the right to health protection and care during pregnancy, in childbirth and after childbirth, including premature one, defined by the international criteria of live birth and stillbirth fetus, using the methods, permitted in the territory of the Republic of Kazakhstan.

      2. Medical, consultative assistance to pregnant women, women in childbirth and new mothers in healthcare organization shall be provided within the guaranteed volume of free medical care.

      3. During pregnancy, the examination, treatment and medical intervention may be performed only with the consent of the woman or her legal representative.

      In cases when delay of screening, treatment and medical intervention threatens the life of a woman and a child (fetus), the decision on screening, treatment and medical intervention shall be taken by a doctor or a medical commission.

**Article 98. Treatment of infertility**

      1. The individuals shall have the right to infertility treatment in healthcare organizations, private medical practitioners, applying safe and effective methods, including the use of auxiliary reproductive techniques and technologies, allowed at the territory of the Republic of Kazakhstan by the authorized body in accordance with legislation of the Republic of Kazakhstan in healthcare area, with the obligatory provision of complete and comprehensive information on their effectiveness, optimal time frames for their appliance, the possible complications, medical and legal implications, and other information, related to their effects on the body.

      2. A married couple shall have the right to use the auxiliary reproductive techniques and technologies upon mutual consent only.

**Article 99. The auxiliary reproductive techniques and technologies, cloning**

      1. Women shall have the right to the auxiliary reproductive techniques and technologies (artificial insemination, in vitro fertilization and embryo implantation).

      2. The order and conditions of the auxiliary reproductive techniques and technologies shall be defined by the authorized body.

      3. When using the auxiliary reproductive techniques and technologies, the prenatal sex selection shall not be allowed, unless the possibility of inheritance of diseases related to sex.

      4. A human embryo may not be obtained for commercial, military and industrial purposes.

      5. Human cloning - reproduction of genetically identical individuals shall be prohibited in the Republic of Kazakhstan.

**Article 100. Health care for surrogacy**

      1. Surrogacy - a bearing and a child birth, including the cases of premature birth, upon the agreement between a surrogate mother (a woman, bearing a fetus after introduction of a donor embryo) and the perspective parents.

      2. A surrogate mother may be a woman of twenty-thirty five years old, received a medical conclusion on a satisfactory state of mental, physical and reproductive health, including the results of medical and genetic testing.

      3. The rights and duties of a surrogate mother, the perspective parents, the rights of the child and the order for concluding an agreement shall be regulated by the legislation of the Republic of Kazakhstan on marriage (marriage) and family.

**Article 101. Donation and storage of germ cells**

      1. The citizens of eighteen - thirty-five years old, who are physically and mentally healthy and passed medical and genetic testing, shall be eligible to be the donors of germ cells.

      2. Donors shall not have a right to receive information about the fate of their donor germ cells.

      3. The procedure and conditions for donation and storage of germ cells shall be approved by the authorized body.

**Article 102. The use of contraception**

      1. Citizens shall have the right to choose contraception methods and means, including medical one, and to refuse them.

      2. The citizens receive a medical assistance on individual selection of suitable contraception methods, taking into account their health status, age and individual characteristics.

**Article 103. Surgical sterilization**

      1. Surgical sterilization as a method of preventing unwanted pregnancy may be conducted to the citizens of not less than thirty-five years old, or those, who at least have two children, and for medical reasons, and with the consent of the full-aged citizen - regardless of his age and presence of children.

      2. Surgical sterilization shall be carried out only upon a written agreement of a patient in the healthcare organizations, by the private medical practitioners, licensed for this activity, with the obligatory prior notification of the patient on irreversibility of the operation.

      3. The procedure and conditions for the surgical sterilization shall be established by the authorized body.

**Article 104. Abortions**

      1. A woman shall have the right to abortion.

      In order to prevent abortion, the doctors shall have to conduct interviews to explain ethical, psychological and physiological adverse effects and possible complications.

      2. Abortions shall be performed at a woman's request if pregnancy is up to twelve weeks, for social reasons - for the pregnancies up to twenty-two weeks, and in medical indications, threatening the life of a pregnant woman and (or) a fetus (in the presence of mono-gene genetic diseases, not-corrective congenital malformations and fatal fetal conditions) - regardless of the gestational age.

      3. Abortions to the minors shall be performed with the consent of their parents or other legal representatives.

      4. In medical and preventive treatment institutions at a woman’s request, medical-social counseling shall be held before and after abortion, including individual choice of methods and means of contraception.

      5. The procedure and conditions for abortion shall be established by the authorized body.

 **Chapter 18. MEDICAL AND SOCIAL CARE FOR TUBERCULOSIS PATIENTS**

**Article 105. Medical care for tuberculosis patients**

      1. Tuberculosis patients shall be subject to mandatory medical care and treatment and shall be provided with the necessary drugs within the guaranteed volume of free medical care.

      2. The patients with infectious tuberculosis shall be subject to mandatory hospitalization, treatment and rehabilitation.

**Article 106. The procedure for recognizing a citizen as a contagious TB patient**

      1. Recognizing a citizen as an infectious tuberculosis patient shall be performed taking into account a medical conclusion of a healthcare organization, the results of laboratory and instrumental testing.

      2. The order of medical examination for recognizing a citizen as an infectious tuberculosis patient shall be established by the authorized body.

      3. The citizen, recognized the infectious tuberculosis patient, may appeal the decision of the healthcare organization to a higher authority, and (or) to the court.

**Article 107. The ground and the order of sending the infectious tuberculosis patients to the mandatory treatment**

      1. Mandatory treatment of citizens suffering from infectious tuberculosis, shall include anti-TB and symptomatic treatment with isolation of patients in the specialized TB institutions.

      2. The ground for mandatory treatment of the citizens, suffering from infectious tuberculosis, shall be their rejection of the treatment, prescribed by a doctor, and recorded in the medical record.

      3. A decision on mandatory treatment of those, suffering from infectious tuberculosis and evading the treatment shall be taken by the court upon recommendations of healthcare bodies (organizations).

      4. The infectious tuberculosis citizens, released from correctional institutions of the criminal-executive system of internal affairs, rejected from voluntary treatment in a written form, shall be sent to mandatory treatment under the court decision, and a month before the release, the prison administration sends relevant documents to the court.

      5. The documents on mandatory treatment shall be considered by the court within five days of their receipt with the participation of the citizen to be sent for compulsory treatment, and a representative of a healthcare organization or a criminal executive system of internal affairs, which has submitted a presentation on mandatory treatment.

      6. The enforcement proceedings bodies shall be charged with enforcement of the court decision on sending the infectious tuberculosis patient to compulsory treatment.

      Footnote. Article 107, as amended by the Law of the Republic of Kazakhstan, dated on 18.01.2012 No 547-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 108. The rights of the infectious tuberculosis patients under mandatory treatment**

      1. The infectious tuberculosis patients under the compulsory treatment, shall invoke all the rights of citizens of the Republic of Kazakhstan with the limitations, associated with the need to comply with the rules of stay in the specialized anti-TB organization.

      2. Sending to compulsory treatment in a specialized anti-TB organization shall not entail a criminal record.

      3. Jobs shall be saved for the patients with infectious tuberculosis, sent to compulsory treatment.

      4. The duration of stay for compulsory treatment shall not interrupt the labor experience and shall be included in the general seniority.

      5. Housing shall be maintained throughout the stay for compulsory treatment for the infectious tuberculosis patients, sent for compulsory treatment and residing in the apartments of the state housing fund.

**Article 109. Treatment and maintenance of the infectious tuberculosis patients in the anti-TB specialized organizations**

      1. Treatment and maintenance of the infectious tuberculosis patients in the specialized anti-TB institutions for compulsory treatment shall be carried out at the expense of the budget funds.

      2. Organization of compulsory treatment, as well as the rules of stay in the specialized anti-TB institutions shall be performed in the order, approved by the authorized body.

      3. Compulsory treatment of the infectious tuberculosis patients shall go on until they stop releasing Mycobacterium tuberculosis, after that they shall be discharged from a hospital to continue treatment on an outpatient basis at the place of residence.

      In the cases of compliance with the requirements to the treatment, under the concilium conclusion, the infectious tuberculosis patient shall be transferred and treated in an anti-TB hospital on an inpatient basis.

**Article 110. Medical surveillance and treatment of infectious tuberculosis patients after compulsory treatment**

      The infectious tuberculosis patients, who passed the mandatory medical treatment, after discharge from a specialized anti-TB institution, shall be registered in an anti-TB organization at the place of residence to receive treatment to exclude recurrence of the contagious tuberculosis disease, in the order, defined by the authorized body.

**Article 111. Social assistance to the infectious tuberculosis patients**

      The infectious tuberculosis patients, discharged from the specialized anti-TB medical organization, in the end of compulsory treatment, shall be provided with employment and living conditions by the local executive bodies.

 **Chapter 19. MEDICAL AND SOCIAL ASSISTANCE TO THE HIV and AIDS- INFECTED PATIENTS**

**Article 112. State guarantees in prevention, diagnosis, and treatment of HIV and AIDS**

      The state shall guarantee to the HIV-infected and AIDS-patients:

      1) the availability and quality of voluntary anonymous and (or) confidential medical examination free of charge, providing dynamic monitoring, psycho-social, legal and medical consultations;

      2) medical care and drug supply within the guaranteed volume of free medical care;

      3) social and legal protection;

      4) prevention of any form of discrimination due to the nature of the disease;

      5) fulfillment of preventive measures to reduce the risk of transmission of HIV infection from mother to fetus.

**Article 113. Social protection of the HIV-infected or AIDS patients**

      1. The children, infected with HIV or suffering from AIDS, shall take training in schools and other educational institutions.

      2. Dismissal from work, refusal to hire, non-admission to kindergartens and schools, as well as the infringement of other rights and legitimate interests of the persons, infected with HIV or AIDS, as well as infringement of housing and other rights of their relatives shall not be allowed.

      3. The persons, infected with HIV or AIDS in the result of improper execution of duties by health professionals and consumer services workers, shall be entitled to receive compensation for the damage, caused to life or health, in accordance with the legislation of the Republic of Kazakhstan.

**Article 114. HIV Prevention**

      HIV prevention measures shall include:

      1) development and implementation of target prevention and education programs for various population groups;

      2) provision of information on epidemic situation of HIV infection and preventive measures through the media;

      3) development and distribution of information materials for various groups of population;

      4) implementation of programs on protection from HIV infection through sex and blood;

      5) opening of the trust points, anonymous testing, psychological, legal and medical counseling;

      6) safety and security arrangements when providing the services, related to the skin penetration.

**Article 115. Testing for HIV**

      1. Citizens of the Republic of Kazakhstan and repatriates shall have the right to pass voluntary anonymous and (or) confidential medical examination and counseling on HIV-infection issues free of charge.

      2. The following individuals shall be subject to mandatory confidential medical examination for HIV infection:

      1) donors and recipients of blood, its components, tissue and (or) organs (parts of organs), germ cells;

      2) the persons, against whom there are reasonable grounds to believe that they are HIV-infected, based on the requests of healthcare organizations, prosecutor’s office, investigation and the court;

      3) the persons on clinical and epidemiological indications in accordance with the regulations, adopted by the Government of the Republic of Kazakhstan.

      3. Foreigners and stateless persons, residing in the territory of the Republic of Kazakhstan, in case of avoiding a medical HIV testing shall be deported from the Republic of Kazakhstan.

      Members of diplomatic, representative and consular institutions of foreign states and other persons in the Republic of Kazakhstan, who enjoy diplomatic privileges and immunities, shall pass a HIV infection testing only with their consent. The offer on the need to pass medical examinations shall be coordinated by the authorized body and the Ministry of Foreign Affairs of the Republic of Kazakhstan.

      4. Examination of minors and incapable persons shall be performed with the consent of their legal representatives or at their request.

      5. Healthcare organizations that revealed the fact of HIV infection in a medical examination, shall notify the patient of the results obtained, inform on the need to observe precaution measures, aimed at protecting his own health and the health of others, and also inform about administrative and criminal liability for failure to treat the infection and contamination of other individuals.

      Footnote. Article 115, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

 **Chapter 20. MEDICAL AND SOCIAL ASSISTANCE TO THE PERSONS WITH MENTAL DISORDERS (DISEASES)**

**Article 116. Voluntariness of mental health seeking behavior**

      1. Mental health care shall include prevention of mental disorders (diseases), examination of mental health, diagnosis of mental disorders, treatment and care, medical and social rehabilitation of those, suffering from mental disorders (diseases).

      2. Psychiatric care shall be provided after the voluntary request of the person with his or her written consent, except for the cases provided for in this Code.

      3. The minors, as well as the person, recognized incapable by the court, shall receive the psychiatric care with the consent of their legal representatives in the order, stipulated by this Code.

**Article 117. Restriction of certain types of professional activity**

      1. A citizen may be found unfit for a while with the right of re-examination because of a mental disorder (illness), to perform certain professional activities, as well as the work, related to the extra-hazardous source.

      Unfitness shall be recognized by the medical commission, created in the specialized mental healthcare organization, licensed and (or) certified for fulfillment of the relevant examination.

      In case of disagreement with the commission’s decision, it may be appealed to the court.

      2. The list of medical psychiatric contraindications for implementing certain professional activities, as well as the work, related to the source of increased danger shall be approved by the Government of the Republic of Kazakhstan and revised taking into account the accumulated experience and scientific achievements at least once every five years.

**Article 118. Protecting the rights and interests of the citizens, receiving psychiatric care**

      1. A citizen, when receiving psychiatric care, shall have the right to invite a representative to protect his legitimate rights and interests. Registration of a representative shall be made in the order, defined by the Criminal Procedure Code of the Republic of Kazakhstan and the Civil Procedure Code of the Republic of Kazakhstan.

      2. The legitimate interests of a minor or a person, recognized incompetent by a court, in receiving the psychiatric care shall be protected by their legal representatives.

      3. The rights and legitimate interests of a citizen, receiving psychiatric care shall be protected by an attorney or a legal representative. The organization’s administration, providing mental health care, shall ensure the possibility of inviting a lawyer, except for the cases, provided in the part 2 of paragraph 3 of Article 97 and paragraph 5 of Article 123 of this Code.

**Article 119. Diagnostics and treatment of mental disorders (diseases)**

      1. Psychiatric care shall be provided by a psychiatrist.

      2. The diagnosis of mental disorder (disease) shall be made by a psychiatrist in accordance with the clinical manifestations, laboratory data and objective information. A person, who was forcibly hospitalized, shall be diagnosed by a commission of psychiatrists. The diagnosis may not be based on disagreement of the citizens with the accepted moral, cultural, political, and religious values, or on other reasons, not related to the mental health status of the person.

3. For diagnosis and treatment of persons suffering from mental disorder (diseases), the medical devices and methods shall be used, allowed by the legislation of the Republic of Kazakhstan in healthcare area.

      4. Medical devices and techniques shall be used for diagnostic and therapeutic purposes only in accordance with the nature of disorders and shall be prohibited for use in the form of punishing a person.

      5. Within forty-eight hours from the time of a psychiatric examination, a physician shall provide a person, suffering from a mental disorder (illness), if he can correctly perceive the provided information, or his legal representative, with the written information on the nature of the mental disorder (disease), the purposes and methods of treatment, and well as the duration of the recommended treatment, possible pains, side effects and the expected results. A special entry shall be made in the medical records on the information provided. In other cases, the information may be provided in accordance with the paragraph 4 of Article 95 of this Code.

      6. Treatment of a person, suffering from a mental disorder (disease) shall be conducted after the receipt of his consent or his legal representatives, except for the cases, provided in paragraph 7 of this Article.

      7. The treatment may be provided without the consent of a person, suffering from a mental disorder (illness), or without the consent of his legal representative only if compulsory medical treatment is applied on the grounds, established by the legislation of the Republic of Kazakhstan, as well as for compulsory hospitalization, taking into account the grounds, specified in paragraph 1 of Article 94 of this Code. In these cases, except for the emergency hospitalization, the treatment shall be provided under the decision of the commission of psychiatrists. During a compulsory hospitalization of a person, a decision on the order of treatment must be taken by the commission of psychiatrists within forty-eight hours since his hospitalization to a psychiatric organization.

      8. A person, suffering from a mental disorder (disease) or his legal representative shall have the right to refuse the proposed treatment or stop it, except for the cases, provided in paragraph 7 of this article.

      9. The person, refused the treatment, or his legal representative shall be explained the possible consequences of stopping the treatment. Refusal of treatment with notification of the possible consequences shall be registered in the medical record and signed by the person with a mental disorder (disease) or his legal representative and a psychiatrist.

      Footnote. Article 119, as amended by the Law of the Republic of Kazakhstan, dated on 29.12.2010 No 375-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 120. The rights of persons with mental disorders (diseases)**

      1. The persons, suffering from mental disorders (diseases), shall have all the rights and freedoms of the citizens, provided by the Constitution of the Republic of Kazakhstan.

      Restriction of the rights and freedoms of citizens, associated with a mental disorder (disease) shall be allowed only in the cases provided by the Laws of the Republic of Kazakhstan.

      2. Every person suffering from mental disorders (diseases), when receiving mental health care shall be entitled to:

      1) receive mental health care at the place of residence, and at the location if necessary;

      2) to refuse from the use of medical devices and methods, scientific research or training, photo, video or filming in any phase of treatment;

      3) invite a specialist, involved in the mental health care provision (with the consent of the latter), to join the medical commission on the issues, regulated by this Code;

      4) study an education program of a secondary or a special school for children with mental development disorder, if the patient is under eighteen years of age;

      5) correspond, send and receive parcels, packages, money, use a telephone, receive visitors, subscribe to periodicals;

      6) possess and purchase daily necessities, and wear his own clothes.

      3. The persons suffering from mental disorders (diseases), who are subject to the compulsory medical treatment in the state specialized mental institutions with intensive supervision, in addition to the rights, specified in paragraphs 1 and 2 of this Article, shall have the rights to:

      1) the acquisition of extra meals;

      2) receipt of additional medical services in excess of the guaranteed volume of free medical care;

      3) the acquisition of soft furniture, clothing, and footwear;

      4) the use of long-distance telephone service;

      5) the use of the cash control account.

      These rights shall be exercised at the expense of the person to whom they are provided.

**Article 121. Compulsory medical treatment for the persons with mental disorders (diseases)**

      1. Compulsory medical measures shall be applied upon the court decision to the persons, suffering from mental disorders (diseases), who committed socially dangerous acts, on the grounds and in the order, defined by the legislation of the Republic of Kazakhstan.

      2. Compulsory medical measures shall be implemented in mental health organizations in the form of:

      1) mandatory outpatient supervision and treatment by a psychiatrist;

      2) compulsory treatment in a mental hospital of common type;

      3) compulsory treatment in a specialized psychiatric hospital;

      4) compulsory treatment in a specialized psychiatric hospital with intensive supervision.

      3. The individuals, hospitalized in a psychiatric hospital for compulsory medical treatment, shall be recognized incapable for the entire period of their stay in a psychiatric hospital.

      4. The money of individuals and legal entities, including pension allowances and the state social benefits shall be credited to the cash control account of the state psychiatric specialized institution with intensive supervision (hereinafter - the institution) to be used by the patients, receiving compulsory treatment in the institution.

      5. The order of the money use shall be specified by the Government of the Republic of Kazakhstan.

      6. Accounting and reporting on the money use of the cash control account of the institution, as well as the control over their use shall be performed in accordance with the legislation of the Republic of Kazakhstan.

**Article 122. Mental health care and social protection, guaranteed by the state**

      1. The state shall guarantee:

      1) emergency and routine mental health care;

      2) psychiatric examination and assessment of temporary incapability;

      3) social help and support in employment of the persons, suffering from mental disorders (diseases), including people with disabilities - in accordance with the individual rehabilitation program.

      2. In order to provide the persons, suffering from mental disorders (diseases), with mental health care and social protection, the state shall:

      1) organize provision of mental health care;

      2) organize general and vocational training of juveniles with mental disorders, including the people with disabilities - in accordance with the individual rehabilitation program;

      3) establish occupational therapy organizations, as well as special productions, workshops or areas with the sheltered employment for occupational therapy, development of new skills for employment of the persons with mental disorders (diseases), including the disabled in these organizations.

**Article 123. Psychiatric examination**

      1. Psychiatric examination shall be conducted in order to reveal mental disorders (diseases) in an examined person, define the need for mental health care and its types, as well as to address the issues of custody and assessment of temporary incapability.

      2. Psychiatric examination, as well as routine examinations shall be conducted at the request or with the written consent of the examined person or with the written request of his legal representatives, indicating the reasons for examination; as for a minor or an incompetent person - at the request or with the written consent of their legal representatives.

      The results of a psychiatric examination and a conclusion on mental health of the examined person shall be recorded in the medical record, indicating the reasons for coming to a psychiatrist and medical recommendations.

      3. In case of objection or if an examined person or a minor does not have a legal representative, the examination shall be performed upon the decision of the guardianship authority, which can be appealed in the court.

      4. The physician conducting the psychiatric examination shall have to introduce himself to the examined person and his legal representative, as a psychiatrist, except for the cases, provided in subparagraph 1) of paragraph 5 of this Article.

      5. Psychiatric examination of a person may be held without his consent or without the consent of his legal representative in the case when the examined person conducts actions, giving a reason to believe that he has a severe mental disorder (disease), causing:

      1) a direct danger to himself or others;

      2) his helplessness, the inability to independently satisfy the survival needs in the absence of proper care;

      3) substantial harm to his health as a result of deteriorating mental condition if a person is left without mental health care.

      6. Psychiatric examination of a person may be held without the consent of his legal representative, if the examined person is under the dynamic supervision, in the order, provided by paragraph 2 of Article 124 of this Code.

      7. Different types of psychiatric expertise and psychiatric examination of a person shall be made in accordance with the legislation of the Republic of Kazakhstan in healthcare area.

      8. In the cases, specified in paragraph 5 of this Article, the decision on psychiatric examination shall be taken by a commission of psychiatrists with notification of the legal representative of the patient.

      9. The decision on psychiatric examination of a person without his consent or without the consent of his legal representative, except for the cases, specified in paragraph 6 of this Article, shall be taken by a psychiatrist at the request, containing the grounds for such an examination, listed in paragraph 5 of this Article.

      10.

excluded by the Law of the Republic of Kazakhstan,dated on 29.12.2010 No 375-IV (shall be enforced upon expiration often calendar days after its first official publication.)

      11.

excluded by the Law of the Republic of Kazakhstan,dated on 29.12.2010 No 375-IV (shall be enforced upon expiration often calendar days after its first official publication.)

      12. An application for a psychiatric examination must be in a written form and contain the detailed information, supporting the need for such an examination, and the data on the person’s refusal (or his legal representative) from visiting a psychiatrist. The psychiatrist may request additional information necessary for a decision making. Having established that the application has no circumstances, specified in paragraph 5 of this Article, a psychiatrist, in a written form, shall reasonably refuse to conduct a psychiatric examination.

      Footnote. Article 123, as amended by the Law of the Republic of Kazakhstandated on 29.12.2010 No 375-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 124. Dynamic monitoring of the persons with mentaldisorders (diseases)**

      1. Dynamic monitoring may be set independently from the consent of a person with a mental disorder (disease), or his legal representative in the cases, specified in paragraph 2 of this Article, and shall include monitoring of the person’s mental health via regular examinations by a psychiatrist and provision of necessary medical and social assistance.

      2. Dynamic monitoring may be set for the person, suffering from chronic disease with severe, persistent, recrudescent symptoms of illness.

      3. The decision on the need to set a dynamic monitoring and its termination shall be taken by a commission of psychiatrists, appointed by the administration of mental health organization, providing outpatient mental health care, or by a commission of psychiatrists, appointed by the healthcare authority, in the amount of no less than three doctors.

      4. A reasoned decision of the commission of psychiatrists shall be recorded in the medical records. The decision on establishment or termination of the dynamic monitoring may be appealed in the order, defined by this Code.

      5. The previously established dynamic monitoring shall stop in recovery or significant and persistent improvement of mental state of the person, suffering from mental disorders (diseases). After the termination of the dynamic monitoring, at the request or with the consent of the person or at the request or with the consent of the legal representative, the psychiatric care shall be provided in the form of counseling and treatment. If mental state of a person with a mental disorder (illness) is changing, the person may be examined without his consent or without the consent of his legal representative on the grounds and in the order, defined in Article 123 of this Code. Dynamic monitoring of mental disorders (diseases) may be resumed in such cases upon the decision of the commission of psychiatrists.

      6. Consideration of termination of dynamic monitoring may be performed in the order, defined by paragraph 3 of this Article, at the initiative of the person, suffering from a mental disorder, as well as at the initiative of his legal representative.

**Footnote. Article 124, as amended by the Law of the Republic of Kazakhstan, dated on 29.12.2010 No 375-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)**

**Article 125. Hospitalization in a psychiatric clinic**

      1. The reason for hospitalization in a psychiatric hospital shall be the presence of a mental disorder (disease) and the decision of the psychiatrist on the need for examination or treatment in a hospital.

      1-1. Mandatory hospitalization to a psychiatric hospital shall be allowed on the basis of the court decision.

      Mandatory hospitalization to a psychiatric hospital before taking a court decision shall be allowed only in order to prevent the consequences, specified in subparagraphs 2), 3) and 4) of paragraph 1 of Article 94 of this Code.

      For each case of mandatory hospitalization without a court decision, within forty-eight hours after the hospitalization to a psychiatric hospital, the hospital’s administration shall send a written notice to the prosecutor.

      If there is information about a spouse, close relatives and (or) legal representatives, within forty-eight hours after hospitalization to the psychiatric hospital, the hospital’s administration shall inform them about it.

      2. Hospitalization to a psychiatric hospital shall be conditioned by the need to conduct a psychiatric examination in the order, defined by the legislation of the Republic of Kazakhstan in healthcare area.

      3. Hospitalization of a person to a psychiatric hospital shall be voluntary at his request or with his written consent, except for the cases, specified in Article 94 of this Code.

      4. A minor shall be hospitalized to a psychiatric hospital with the written consent of his parents or other legal representative.

      5.

excluded by the Law of the Republic of Kazakhstan, dated on 29.12.2010 No 375-IV (shall be enforced upon expiration often calendar days after its first official publication.)

      6. In case of objection or absence of a legal representative, a minor’s hospitalization to a psychiatric hospital shall be conducted upon the decision of the guardianship authority, which may be appealed to the court, with a written notification of the prosecutor within twenty-four hours since the decision on hospitalization shall be taken.

      7. The obtained consent of a person for hospitalization shall be recorded in the medical record, and signed by the person or his legal representative and by a psychiatrist.

      8. The person’s mandatory stay in a psychiatric hospital shall last until the grounds for hospitalization maintain.

      9. The person, hospitalized in a psychiatric hospital forcedly, within the first six months of the stay, not less than once a month shall be examined by a commission of psychiatrists to resolve the issue on prolongation of hospitalization. Prolongation of hospitalization for more than six months shall be decided by the court at the request of the commission of psychiatrists in the order, defined the legislation of the Republic of Kazakhstan in healthcare area.

      10. An extraordinary examination of a forcedly hospitalized person may be performed at the request of the patient or his legal representative, a lawyer.

      A person, hospitalized to a psychiatric hospital on the grounds, specified in paragraph 1 of Article 94 of this Code, shall be subject to mandatory examination within forty-eight hours since hospitalization, by the commission of psychiatrists of the mental health organization, which takes a decision on reasonability of hospitalization. In the cases when hospitalization is considered unreasonable and the hospitalized person does not want to stay in a psychiatric hospital, it is subject to immediate discharge from the hospital.

      11. In case of disagreement with the forced hospitalization, the person, suffering from mental disorders (diseases), or his legal representative shall be entitled to appeal to the court.

      Footnote. Article 125, as amended by the Law of the Republic of Kazakhstan, dated on 29.12.2010 No 375-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 126. Examination of a minor or a person, recognized incapable by a court,placed in a psychiatric hospital at the request or with the consent of their legal representatives**

      1. A minor or a person, recognized incapable by the court, placed in a psychiatric hospital shallbe subject to mandatory examination by a commission of psychiatrists of a mental health organization in the order, specified by Article 123 of this Code.

      2. During the first six months, a minor or a person, recognized incapable by the court shall be subject to examination by a commission of psychiatrists at least once a month to resolve the issue on prolongation of hospitalization. The decision on prolongation of the hospitalization for more than six months shall be made by the court at the request of the commission of psychiatrists in the order, defined by the legislation of the Republic of Kazakhstan in healthcare area.

      3. In case if the commission of psychiatrists or the psychiatric hospital’s administration shall find out violations, committed during hospitalization by the legal representatives of a minor or a person, recognized incapable by a court, within twenty-four hours since revealing the said circumstances, the psychiatric hospital’s administration shall notify about it the prosecutor and the guardianship authority at the place of residence of the patient.

      Footnote. Article 126, as amended by the Law of the Republic of Kazakhstan, dated on 29.12.2010 No 375-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 127. Security measures in providing psychiatric care**

      1. Inpatient mental health care shall be provided in the least restrictive conditions, ensuring safety of the hospitalized person and other persons, and observance of his rights and legitimate interests by the medical staff.

      2. Measures of physical restraint and isolation in the forced hospitalization and stay in a psychiatric hospital shall be applied in the cases, forms and time, when, according to a psychiatrist, other methods shall not be able to prevent the actions of the hospitalized person, dangerous to him or others and shall be performed under the permanent supervision of medical personnel. The forms and time of applying the physical restraints or isolation shall be recorded in the medical record with the notice of his legal representative.

      3. Law enforcement officials shall be obliged to assist medical staff in implementing compulsory examination,mandatory hospitalization, provide safe access to the hospitalized person for his examination and also in the cases, when the hospitalized person (the person subject to hospitalization) threatens life and health of others.

      Footnote. Article 127, as amended by the Law of the Republic of Kazakhstan, dated on 29.12.2010 № 375-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 128. Discharge from the psychiatrichospital**

      1. Discharge from the psychiatric hospital shall be made upon the patient’s recovery or improvement of his mental state, when further inpatient treatment shall not be required, and after completion of examination or expertise, which were the grounds for hospitalization.

      2. Discharge of the patient, voluntarily staying in a psychiatric hospital shall be made at his personal application, a request of his legal representative or under the decision of his attending physician.

      3. Discharge of the patient, hospitalized in a psychiatric hospital by force shall be made upon the conclusion of the commission of psychiatrists, court decision or prosecutor’s resolution.

      4. The patient to whom mandatory medical measures were applied under the court decision shall be discharged from the hospital under the court's ruling only.

      5. The patient, hospitalized in a psychiatric hospital voluntarily, may be refused to be discharged from the hospital, if the commission of psychiatrists of a mental health organization will find out the grounds for mandatory hospitalization, specified in paragraph 1 of Article 94 of this Code. In this case, the issues about his stay in the hospital, prolongation of hospitalization and discharge from the hospital shall be resolved in the order, defined by paragraphs 8 – 10 of Article 125, paragraph 3 of this Article.

      Footnote. Article 128, as amended by the Law of the Republic of Kazakhstan, dated on 29.12.2010 No 375-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 129. Reasons for hospitalization to the psycho-neurological organization**

      1. The reason for hospitalization of a minor to the psycho-neurological organization shall be the conclusion of the psychological, medical and educational counseling; for the person, declared incompetent by the court - a decision of the guardianship authority, based on the conclusion of the medical commission with participation of a psychiatrist.

      Hospitalization of an adult with a mental disorder (disease) to the psycho-neurological organization, who is not recognized as incapable shall be performed under the court decision.

      The conclusion should confirm the presence of a mental disorder (disease), depriving the person of the opportunity to be in a non-specialized organization for social welfare, and for the person’s legal capacity - the data on absence of the grounds for raising the issue on recognizing him incapable in the court.

      2. Guardianship authorities shall be obliged to take measures to protect property interests of the persons, hospitalized to a psycho-neurological organization.

      3. The ground for sending a minor to a psycho-neurological organization for special education shall be the presence of a mental disorder (disease). Sending shall be made at the request of the parents or his legal representative and shall be based on the conclusion of republican, regional or urban psychological, medical and educational consultations. The conclusion should contain the ground for training the minor in a special school for the children with mental development disorder.

      4. The ground for transfer of a person, suffering from a mental disorder (disease), from a psycho-neurological organization or a special mental school to the similar organization of common type shall be the conclusion of the medical commission with participation of a psychiatrist, psychological, medical and educational consultation on absence of medical indications for living or training in a specialized psycho-neurological organization.

      5. Discharge from a psycho-neurological organization or a special education school shall be made:

      1) at the personal request of the person with a mental disorder (disease), with the presence of a conclusion of the medical commission with participation of a psychiatrist, confirming that the person is able to live independently;

      2) at the request of the parents, other relatives or a legal representative, ready to take care of the discharged minor or of the person, recognized incapable by the court.

      Footnote. Article 129, as amended by the Law of the Republic of Kazakhstan, dated on 29.12.2010 No 375-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)

 **Chapter 21. MEDICAL AND SOCIAL ASSISTANCE TO THE PATIENTS, SUFFERING FROM ALCOHOL, DRUG ADDICTION AND SUBSTANCE ABUSE**

**Article 130. Medical care for the patients, suffering from alcoholism, drug addiction and substance abuse**

      1. The state shall provide a system of measures for prevention and treatment of alcohol, drug addiction and substance abuse.

      2. Compulsory medical measures shall be applied under the court decision in respect of the persons, who committed offenses and need medical treatment from alcoholism or drug addiction or substance abuse, as well as to the persons who have committed an administrative offense and are recognized as the patients, suffering from chronic alcoholism, drug addiction or substance abuse and evading voluntary treatment.

**Article 131. Treatment of patients, suffering from alcohol, drug addiction and substance abuse in medical institutions and those, needing medical and social rehabilitation**

      1. Medical and social rehabilitation of the persons, suffering from alcoholism, drug addiction and substance abuse, shall be voluntary when seeking medical care in health care organizations, providing drug treatment and, at the request of the patient, it can be anonymous.

      2. A minor, suffering from alcoholism, drug addiction and substance abuse, and a drug addict, acknowledged by a court to be legally incapable, shall receive a medico-social rehabilitation with the consent of their legal representatives.

**Article 132. A procedure for recognizing a person as alcohol, drug addict and substance abuser**

      1. Recognition of a person as an alcohol, drug addict and substance abuser shall be performed by the state healthcare organizations after proper medical examination and in the order, defined by the authorized body.

      2. In case of disagreement of the person with recognizing him an alcohol, drug addicted and substance abuser, such a decision may be appealed to a higher healthcare governing body and (or) to the court.

**Article 133. The rights of the persons suffering from alcoholism, drug addiction and substance abuse**

      1. The persons, suffering from alcohol, drug addiction and substance abuse shall be entitled to:

      1) receive qualitative medical care;

      2) choose a drug treatment organization;

      3) receive information about their rights, the nature of their substance abuse disorders, the methods of treatment, medical and social rehabilitation;

      4) receive medical and social rehabilitation at the place of residence, and at the location if necessary.

      2. A drug addict or his legal representative shall have the right to refuse the proposed medical and social rehabilitation at any stage.

      3. The person, refused medical and social rehabilitation, or his legal representative shall be explained the possible consequences of rejection from the medical and social rehabilitation. Refusal of the medical and social rehabilitation and explanation of the possible consequences are recorded in the medical record and signed by the drug addict or his legal representative and by the addiction psychiatrist.

      4. It shall be prohibited to restrict the rights and freedoms of drug addicts, just by virtue of having the diagnosis of drug addiction, the fact of being under dynamic supervision of a drug treatment organization, except for the cases, provided by the Laws of the Republic of Kazakhstan.

**Article 134. Record and surveillance of the alcohol and drug addicts and substance abusers**

      The persons, recognized as suffering from alcohol, drug addiction and substance abuse, shall be subject to registration and supervision in health care organizations at the place of residence and receive supportive treatment there in the order, defined by the authorized body.

 **Chapter 22. MEDICAL ASSISTANCE TO CERTAIN CATEGORIES OF CITIZENS**

**Article 135. Provision of medical assistance to the military servicemen, space flight candidates, cosmonauts, workers of special state and law enforcement bodies, members of their families and the retirees of these bodies**

      Footnote. The title, as amended by the Laws of the Republic of Kazakhstan dated on 06.01.2011 No 379-IV (shall be enforced upon expiration often calendar days after its first official publication); dated on 06.01.2012 No 529-IV (shall be enforced upon expiration oftwenty one calendar days after its first official publication); dated on 13.02.2012 No 553-IV (shall be enforced upon expiration often calendar days after its first official publication.)

      1. Military servicemen, space flight candidates, cosmonauts, members of special government agencies and law enforcement officials, their family members and retirees of these bodies shall receive medical care in accordance with the Laws of the Republic of Kazakhstan.

      2. In their absence at the place of service or at the place of residence or in the absence of special departments in medical organizations, specialists or special equipment, the medical care shall be provided in medical institutions within the guaranteed volume of free medical care.

      Footnote. Article 135, as amended by the Laws of the Republic of Kazakhstan dated on 06.01.2011 No 379-IV (shall be enforced upon expiration often calendar days after its first official publication); dated on 06.01.2012 No 529-IV (shall be enforced upon expiration oftwenty one calendar days after its first official publication); dated on 13.02.2012 No 553-IV (shall be enforced upon expiration often calendar days after its first official publication.)

**Article 136. Medical assistance to the citizens, who were exposed to ionizing radiation**

      1. The citizens, exposed to ionizing radiation, shall receive medical care in accordance with the Laws of the Republic of Kazakhstan.

      2. The order of sampling, storage and use of blood and tissues of those, exposed to ionizing radiation shall be established by the Government of the Republic of Kazakhstan.

**Article 137. Medical assistance to the citizens, injured by environmental disaster**

      1. The citizens - victims of ecological disaster - the categories of persons, specified by the Laws of the Republic of Kazakhstan.

      2. The citizens, who were the victims of environmental disasters, shall receive medical care in accordance with the Laws of the Republic of Kazakhstan.

**Article 138. Medical assistance to the citizens, whose freedom is limited**

      Freedom limited and persons serving a sentence in prison and placed in special institutions, shall receive the medical care in the order, defined by the authorized body and other state bodies within their competence, established by the Laws of the Republic of Kazakhstan.

 **Chapter 23. REGULATION OF CERTAIN RELATIONSHIPS IN HEALTHCARE SYSTEM**

**Article 139. The procedure of surgery, blood transfusions, its components and application of invasive diagnostic techniques**

      1. Surgery, blood transfusion, its components and appliance of invasive diagnostic techniques shall be used with the written consent of the patients.

      People, suffering from mental disorders (diseases), recognized by the court as legally incapable, and the minors shall receive surgery, blood transfusion and its components, invasive diagnostic methods with the written consent of their legal representatives.

      2. The consent may be withdrawn, except for the cases when for the health reasons the medical professionals have already started surgery and its termination is impossible because of the threat to the life and health of the patient.

      3. In the cases when a delay of a surgery, blood transfusion and its components, invasive diagnostic techniques threaten the patient's life, and to obtain the consent of the patient or his legal representative is impossible, the decision shall be taken by a doctor or a concilium, followed by informing the patient or his legal representatives on the measures taken.

**Article 140. Confirmation of biological death. Conditions for termination of artificial life sustaining measures**

      1. Biological death - the cessation of functioning of a body when its vital functions have failed irreversibly.

      2. Biological death shall be ascertained by a medical professional taking into account all the following symptoms:

      1) cardiac arrest;

      2) respiratory arrest;

      3) termination of the functions of the central nervous system.

      3. Artificial life-support measures may be terminated only if:

      1) biological death is pronounced;

      2) irreversible brain death is recorded by a concilium, under the unanimous written consent of close relatives and (or) legal representatives.

**Article 141. Euthanasia**

      Implementation of euthanasia shall be prohibited.

**Article 142. Anatomical gift**

      1. Anatomical gift - a voluntary donation of tissues and (or) organs (parts of organs) by a capable person both in life and after his death, performed by a person under the duly settled contract or a last will.

      2. Information about the anatomical gift shall not be disclosed.

      3. As an anatomical gift, in addition to the willed tissues and (or) organs (parts of organs) shall be recognized the corpses, that were not identified and claimed within forty-five days from the date of their detection.

      4. Anatomical gift may be used in scientific, research and practice and training purposes to conduct biomedical research.

      5. The order and conditions for transmission of an anatomical gift to the healthcare organizations shall be defined by the Government of the Republic of Kazakhstan.

 **SECTION 6. ACTIVITIES IN HEALTHCARE AND EPIDEMIOLOGICAL WELFARE AND PROTECTION OF PUBLIC HEALTH**

 **Chapter 24. ACTIVITIES IN HEALTHCARE AND EPIDEMIOLOGICAL WELFARE OF THE POPULATION**

**Article 143. The system of state Healthcare and epidemiological service**

      The unified system of the state healthcare-epidemiological service shall include:

      1) the state body for healthcare and epidemiological welfare of the population;

      2) structural units of other state bodies, working in healthcare and epidemiological welfare of the population;

      3) the state organizations, working in healthcare and epidemiological welfare of the population.

**Article 144. State healthcare-epidemiological regulation**

      1. State healthcare-epidemiological regulation - the activity of healthcare-epidemiological service, which includes:

      1) development of uniform standards for improvement of healthcare epidemiological regulation and control over their development;

      2) development (improvement), examination, approval and publication of documents of healthcare and epidemiological regulation;

      3) research, generalization of application practice, control over application of the documents on healthcare and epidemiological regulation;

      4) formation and keeping of a single data bank of the documents on healthcare and epidemiological regulation;

      5) harmonization of healthcare and epidemiological regulation documents with the generally accepted international standards.

      2. The documents on the state healthcare-epidemiological regulation shall be the healthcare rules and hygienic standards, instructions, guidelines, procedures, orders, technical regulations, rules and standards.

      3. The order of development and approval of the documents on state healthcare and epidemiological regulation, except for healthcare and hygienic standards, shall be approved by the authorized body.

      4. Healthcare regulations shall be the regulatory legal acts for healthcare and epidemiological welfare of the population, establishing the healthcare and epidemiological requirements (including the safety criteria, and (or) the safety of environmental factors, business and other activities, products, works and services to the people), violation of which shall pose a threat to human life or health, as well as the threat of emergence and spread of diseases.

     5. Health standard - the established by researches, permissible maximal or minimal quantitative and (or) qualitative value of an indicator on a particular environmental factor from the perspective of its safety and (or) harmlessness to the people.

      6. Regulatory legal acts in healthcare and epidemiological and hygienic standards shall be mandatory for all individuals and legal entities in the territory of the Republic of Kazakhstan.

      7. When developing and approving the regulatory legal acts on healthcare and epidemiological welfare of the population, the state bodies shall be obliged to adjust them with the authorized body.

      Footnote. Article 144, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 145. Healthcare and epidemiological requirements**

      Healthcare rules, hygienic standards shall set healthcare and epidemiological requirements to:

      1) the maintenance and operation of industrial, public, residential and other premises, buildings, structures, equipment and vehicles;

      2) the choice of a land plot for construction;

      3) the design, construction, reconstruction, repair and commissioning and maintenance of the facilities;

      4) the products for industrial purposes;

      5) the products for household and hygienic purposes and technologies of their production;

      6) the food and food ingredients, conditions of their production, packaging, transportation, storage, sale, disposal and destruction;

      7) the products imported to the territory of the Republic of Kazakhstan, to the organization and control over the genetically modified and hazardous chemicals, contained in the products, including persistent organic pollutants;

      8) organization of a special, therapeutic and preventive, baby, diet food and public catering;

      9) the use of chemicals, toxins, biological agents and materials;

      10) the water sources (water intakes for drinking purposes), domestic water supply and the places of cultural and utility water use and safety of water facilities;

      11) the ambient air in urban and rural settlements, at the territories of industrial organizations, the air, microclimate of production, residential and other facilities;

      12) the soils and their security, maintenance of urban and rural settlements, industrial and construction sites;

      13) the collection, use, application, disposal, transportation, storage and disposal of production and consumption wastes;

      14) the working conditions, consumer services, medical care, special and preventive nutrition;

      15) the conditions of work with biological and chemical agents, toxins, biological and microbiological organisms and their toxins;

      16) the conditions of work with the sources of physical factors, affecting the people;

      17) conditions of education, training, living and on-the-job training of different groups of population;

      18) hygienic education and training of the population;

      19) provision of radiation, chemical, microbiological, toxicological, parasitological safety;

      20) technical standard documentation (standards, standards of organizations, regulations, prescriptions), developed for works and services, new types of raw materials, manufacturing equipment and processes, tools, food raw materials and food products, construction materials, sources of ionizing radiation, packaging and chemical, biological and medicinal products, packaging materials and resins, perfumes, cosmetics, printing products and other consumer goods;

      21) the organization and fulfillment of works and services, including development, testing, production, manufacturing, storage, transportation, sale, use of disinfection, disinfestation and deratization devices, equipment, materials, maintenance and operation of disinfection objects, and monitoring of effectiveness and safety of works and services;

      22) the conditions of sterilization and disinfection of medical devices;

      23) the conditions of industrial production of drugs;

      24) iodization of white salt and enrichment (fortification) of food;

      25) the application and use of potentially hazardous chemical and biological agents, and assessment of their maximum allowable concentrations;

      26) organization and fulfillment of healthcare anti-epidemic (preventive) measures, including the healthcare protection of the territory of the Republic of Kazakhstan, introduction of restrictive measures, including quarantine, in respect of the patients, suffering from infectious and parasitic diseases, the medical examinations and vaccinations of the population;

      27) the storage and processing of raw materials;

      28) water supply, sewerage, lighting and ventilation of facilities;

      29) the conditions of transportation and storage of goods, toxic substances;

      30) the conditions of passengers transportation;

      31) liquidation, conservation, conversion of facilities;

      32) production control;

      33) the application and use of biologically active supplements.

      Footnote. Article 145, as amended by the Law of the Republic of Kazakhstan dated on 03.12.2011 No 505-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 146. The state registration, re-registration and revocation of a decision on the state registration of food products and certain types of products and substances, that have harmful effects on human health**

      1. Food products and certain types of products and substances, that have harmful effects on human health shall be subject to the state registration in a state body for healthcare and epidemiological welfare of the population, including:

      1) baby food, nutritional and biologically active supplements, genetically modified objects, dyes, disinfection, disinfestation and deratization devices, materials and things, contacting with water and food products, produced (made) and imported to the territory of the Republic of Kazakhstan for the first time;

      2) substances and materials and drugs, containing these substances and posing a potential risk to the population, imported to the territory of the Republic of Kazakhstan and introduced in production for the first time, and previously untapped.

      2. The state registration of food products shall be performed in accordance with the Law of the Republic of Kazakhstan "On Food Safety."

      3. The state registration of certain types of products and substances that have harmful effects on human health shall be conducted on the basis of:

      1) an expert hazard assessment of substances and certain types of products for the population and the environment;

      2) compliance with the normative legal acts on healthcare and epidemiological welfare and the health standards of substances, the separate components of a product;

      3) development of special measures, including recycling and disposal of substances and certain types of products, to prevent their harmful effects on people and the environment.

      4. The procedure for the state registration, re-registration and revocation of a decision on the state registration of baby food, food and dietary supplements, genetically modified objects, dyes, disinfection, disinfestation and deratization devices, materials and things, contacting with water and food, chemicals, certain types of products and substances that have harmful effects on human health shall be established by the authorized body.

      5. The costs, associated with a healthcare-epidemiological expertise and a scientific rationale of food products and certain types of products and substances that have harmful effects on human health, shall be covered by the applicants for registration and re-registration of the products.

      6. The list of substances and products, registered and approved for use in the Republic of Kazakhstan, shall be published in the print media.

**Article 147. Healthcare-epidemiological monitoring**

      1. Healthcare-epidemiological monitoring - the state system for supervising the public health and the environment, their analysis, evaluation and prognosis, as well as the establishment of cause-and-effect relationship between the health status of the population and the impact of environmental factors.

      2. Healthcare-epidemiological monitoring shall be performed by the state bodies and organizations of healthcare-epidemiological service in the order, defined by the authorized body.

**Article 148. Prevention of emergence and spread of infectious and parasitic diseases, poisoning of the population**

      1. In order to prevent the emergence and spread of infectious and parasitic diseases, poisoning of the population, the healthcare – anti-epidemic (preventive) measures shall be taken, provided by the documents of the state healthcare-epidemiological regulation system, including healthcare protection of the territory of the Republic of Kazakhstan, introduction of restrictive measures, including quarantine, production control, with respect to the persons, suffering from infectious and parasitic diseases, organization of medical examinations, vaccinations, hygiene training of the population.

      2. Healthcare and anti-epidemic (preventive) measures shall be included in the programs for territorial development and other regional programs.

      3. The patients with infectious and parasitic diseases, the persons, suspected of infectious and parasitic diseases, bacilli-carriers shall be subject to isolation and treatment, and those, who communicated with them – to the medical supervision and isolation and treatment if necessary.

      4. The patients with chronic infectious and parasitic diseases, chronic bacilli-carriers, dangerous to others, shall be subject to temporarily suspension from work in accordance with the labor legislation of the Republic of Kazakhstan.

      Footnote. Article 148 as amended by the Law of the Republic of Kazakhstan dated on 03.07.2013 No. 124-V (shall be enforced upon expiration of ten calendar days after its first official publication).

**Article 149. Healthcare protection of the territories of the Republic Kazakhstan**

      1. The checkpoints of the state borders of the Republic of Kazakhstan, coinciding with the customs border of the Customs Union, except for the automobile checkpoints, shall have healthcare and quarantine stations for healthcare and quarantine supervision of passengers, train staffs, vehicles, cargos that are hazardous to the population’s health.

      2. Healthcare and quarantine supervision at the checkpoints (healthcare-quarantine stations) at the state border of the Republic of Kazakhstan shall be performed by the territorial units of the state body for healthcare and epidemiological welfare of the population.

      In the automobile checkpoints at the state border of the Republic of Kazakhstan, the healthcare and quarantine supervision shall be conducted by the customs authorities of the Republic of Kazakhstan.

      3. It shall not be permitted to import dangerous cargos and goods into the territory of the Republic of Kazakhstan, prohibited for importation, as well as the cargos and goods in respect of which the healthcare and quarantine supervision found out that their importation to the territory of the Republic of Kazakhstan would cause the emergence and spread of infectious diseases or mass noncommunicable diseases and poisoning.

      Footnote. Article 149, as amended by the Laws of the Republic of Kazakhstan dated on 30.06.2010 No 297-IV (the order of enforcement see Article 2); dated on 06.01.2011 No 378-IV (shall be enforced upon expiration often calendar days after its first official publication).

**Article 150. Terms for introduction of restrictive measures, including quarantine, in case of a threat of emergence of epidemics of infectious diseases**

      1. In case of a threat of importation and spread of infectious and parasitic diseases, in accordance with this Code, the authorized body at state border checkpoints of the Republic of Kazakhstan, coinciding with the customs border of the Customs Union, and at the relevant territories, shall impose restrictive measures, including quarantine, with the special conditions for business and (or) other activities and life of the population.

      2. Operational guidelines for coordination of central and local executive bodies, individuals and legal entities in the cases of introducing the restrictive measures, including quarantine, shall be entrusted to the state inter-departmental commission for prevention and elimination of emergency situations and the territorial emergency commissions.

      3. Restrictive measures, including quarantine, at the separate objects, shall be introduced (canceled) upon the decision of the chief state healthcare doctor of the relevant territory (transport), or his deputies, as well as at the departmental facilities - by the head of departments of the state bodies, operating in healthcare and epidemiological welfare of the population.

      4. The procedure of implementing the restrictive measures, including quarantine, and the list of infectious diseases, with the threat of the emergence and spread of which the restrictive measures are introduced, including quarantine shall be established by the Government of the Republic of Kazakhstan.

      Footnote. Article 150, as amended by the Law of the Republic of Kazakhstan, dated on 30.06.2010 No 297-IV (shall be enforced from 01.07.2011).

**Article 151. Registration and investigation of cases of infectious and parasitic, occupational diseases and poisonings**

      1. All cases of infectious and parasitic diseases, occupational diseases and poisonings shall be subject to registration in health care organizations at the place of detection, the state registration and reporting by the state bodies and organizations of healthcare-epidemiological service. The order of registration, record-keeping of the said cases of diseases and poisoning, as well as the procedure of recording them shall be established by the authorized body.

      2. The cases of infectious and parasitic diseases, occupational diseases and poisoning of the population shall be investigated by the specialists of healthcare-epidemiological service in the order, specified by the authorized body.

**Article 152. Disinfection, disinfestation and deratization actions**

      1. In order to prevent the emergence, spread of infectious and parasitic diseases, the individual entrepreneurs, individuals and legal entities shall be required to conduct a set of measures to eliminate infectious and parasitic diseases (disinfection), insects and other arthropods (pest control), and deratization (extermination of rodents) at their own expense and upon the epidemiological indications, regulations, and instructions of the officials of healthcare-epidemiological service.

      2. In case of epidemic emergencies at the expense of budget funds, the extraordinary compulsory disinfection, disinfestation and deratization measures shall be taken under the decision of local executive bodies of regions, city of republican significance and the capital upon the recommendation of the state bodies of the healthcare-epidemiological service.

      3. Focal disinfection shall be carried out by medical organizations as well as the organizations of healthcare-epidemiological service.

 **Chapter 25. PROTECTION OF PUBLIC HEALTH**

**Article 153. The purpose and types of disease prevention**

      1. To prevent disease is to prevent occurrence or progression of diseases, as well as their effects and complications.

      2. Disease prevention shall be divided into primary, secondary and tertiary preventions.

      Primary prevention of diseases (mass and individual) shall be aimed at creation of favorable living conditions in order to prevent the occurrence of diseases.

      Secondary prevention shall be aimed at prevention of diseases’ progression in the early stages and their consequences.

      Tertiary prevention shall be aimed at controlling of the already developed complications, damage of organs and tissues.

**Article 154. Promotion of a healthy lifestyle**

      1. A healthy lifestyle shall include promotion of healthy lifestyles, healthy food and disease prevention through information management, hygienic education in improving health and prevention of diseases, related to the lifestyle.

      2. A healthy lifestyle shall be promoted by healthcare organizations, coordinated and guided by the authorized body together with other government agencies, with participation of international and public organizations.

**Article 155. Medical examinations**

      1. The main goals of medical examinations shall provide timely medical examination, aimed at improvement of health, detection and prevention of a disease spread, including occupational diseases, poisoning, accidents, and ensure labor safety and health protection of employees of organizations, and the persons, conducting economic and (or) production activities.

      2. Medical examinations may be mandatory and preventive.

      3. Mandatory medical examinations shall be divided into preliminary and periodic.

      Preliminary mandatory medical examinations shall be conducted for admission to work or school to assess fitness for work or studies, as well as prevention of general, occupational and non-infectious and parasitic diseases.

      Mandatory periodic medical examinations shall be conducted to ensure a dynamic monitoring of the health status of employees, the timely detection of initial symptoms of diseases, prevention of general, occupational and non-infectious and parasitic diseases.

      4. The list of occupational hazards, occupations, where mandatory medical examinations are conducted, as well as the procedure and frequency of these examinations shall be established by the Government of the Republic of Kazakhstan.

      5. The employers, at their own expense, shall arrange timely mandatory periodic medical examinations for workers, subject to the examinations, in accordance with the legislation of the Republic of Kazakhstan in healthcare area.

      6. Medical examinations shall be divided into mass and selective.

      Mass medical examinations shall be conducted via a continuous method to the target population groups in order to detect diseases at the early stages and prevent development of diseases, risk factors, causing emergence of diseases, formation and improvement of public health.

      Selective medical examinations shall be carried out for a dynamic monitoring, implementation of a set of measures for treatment and rehabilitation of those, suffering from certain diseases or at risk.

      7. Target groups, subject to preventive medical check-ups, as well as the order and frequency of these examinations shall be established by the authorized body, taking into account the proven scientific data on their efficacy, safety and cost-effectiveness.

      8. Employers shall create conditions for taking preventive medical examinations for the persons, subject to the examinations, in accordance with the list of the guaranteed volume of free medical care, approved by the Government of the Republic of Kazakhstan.

      9. Individual entrepreneurs and legal entities, engaged in production and business activities, shall not admit to work the persons, who have not passed the preliminary and periodic medical examinations or unfit to work for health reasons.

      10. The procedure for issuance, recording and keeping of personal medical records shall be defined by the Government of the Republic of Kazakhstan.

      11. Timeliness of mandatory and preventive medical examinations shall be controlled by the state bodies, working in healthcare and epidemiological welfare of the population, provision health services, and the state labor inspectors of the authorized body for labor.

      Footnote. Article 155, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 156. Preventive vaccination**

      1. The individuals, who are in the territory of the Republic of Kazakhstan, shall have to be vaccinated against infectious and parasitic diseases within the frames of the guaranteed volume of free medical care.

      2. The list of diseases against which vaccinations shall be held, the order, time-frames and population groups, subject to routine immunization, shall be defined by the Government of the Republic of Kazakhstan.

      3. Storage, transportation and use of prophylactic (immunobiological, diagnostic, disinfectants) drugs shall be performed in the order, established by the Government of the Republic of Kazakhstan.

      4. Preventive (immunobiological, diagnostic, disinfectants) drugs, purchased by the local state healthcare management bodies of regions, city of republican status and the capital, shall be stored at the warehouses of the authorized body.

      Footnote. Article 156, as amended by the Law of the Republic of Kazakhstan, dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011).

**Article 157. Prevention of non-communicable diseases, including occupational diseases and injuries**

      1. Prevention of non-communicable diseases, including occupational, shall include:

      1) prevention of behavioral risk factors for diseases and improvement of medical literacy through:

      promotion of a healthy lifestyle and healthy eating;

      informing of the population through the media, educational programs on prevention of diseases;

      organization of health schools to train the necessary self-help techniques to those, suffering from chronic non-communicable diseases;

      2) monitoring of disease risk factors of the attached population by the primary health care specialists, occupational diseases of workers – by the specialists of the state bodies, working in healthcare and epidemiological welfare of the population;

      3) minimization of impact of industrial disease risk factors by the state bodies within their powers, other agencies and organizations, as well as individual entrepreneurs;

      4) detection of those, suffering from chronic non-communicable diseases, including occupational, via conduction of medical examinations and motivation of earlier ambulation;

      5) dynamic monitoring and timely rehabilitation of the persons with chronic diseases, including occupational, including outpatient drug supply of certain categories of citizens, rehabilitation treatment, and medical and social rehabilitation;

      6) temporary transfer to an easier job for health reasons for the period of time, specified in the medical certificate, in accordance with the order, approved by the authorized body.

      2. Injury prevention shall be performed at the inter-sectorial level by the state bodies within their powers, by the individuals and legal entities.

**Article 158. Prevention of substance abuse**

      1. Prevention of substance abuse shall include:

      1) promotion of information about the danger of substance abuse, as well as medical, social and legal aspects of their use;

      2) prohibition of advertising in hallucinogenic drug circulation area, promotion of the ways, methods of development, manufacturing and use, the places for purchase of psychoactive substances, as well as limiting of advertising the samples of pharmaceuticals, containing narcotic drugs, psychotropic substances and precursors in the specialized medical publications;

      3) preventive monitoring and registration of risk individuals with mental and behavioral disorders (diseases), caused by the psychoactive substances use;

      4) voluntary, anonymous treatment of the persons, addicted to psychoactive substances;

      5) voluntary medical and social rehabilitation of drug addicts.

      2. Prevention of substance abuse shall be performed by all individual and legal entities within their competence.

**Article 159. Prevention and restriction of tobacco smoking, alcoholism**

      1. Prevention and restriction of tobacco smoking, alcohol addiction shall be aimed at protection of health, introduction of the age limit for the persons, eligible to buy tobacco, alcohol products, formation of public attitude to smoking and alcohol drinking as a risk factor for life and health, organization of the agreed activities to prevent the spread of smoking, alcoholism.

      2. Sale of tobacco products shall be prohibited:

      1) to the persons and by the persons under the age of eighteen years;

      2) from open packets of tobacco products or unit sales;

      3) without the direct involvement of a seller, through vending machines, electronic or other mechanical devices;

      4) in the facilities and at the territories of institutions of healthcare, education, sports and recreation, sport and sport-technical facilities, stadiums;

      5) without the appropriate documents, certifying the quality of products;

      6) without excise stamps or accounting and control marks;

      7) if a pack of tobacco products contains less than twenty cigarettes;

      8) without the data on composition, the levels of tar, nicotine, and at least three harmful components - systemic poisons, carcinogenic and mutagenic substances, printed on a pack of tobacco product and a packaging of tobacco product. The order of printing of the data on composition, the levels of tar, nicotine and other poisons, systemic, carcinogenic and mutagenic substances on a pack of tobacco product and on a packaging of tobacco product shall be approved by the Government of the Republic of Kazakhstan;

      9) without the warnings, printed on a pack of tobacco product;

      10) without the printed information on prohibition to sell the tobacco products to the persons under eighteen years of age;

      11) for a pack of tobacco products, the packaging of which contains the words "low-tar", "light", "ultra-light" or "mild" or other phrases, including in foreign languages, creating a false impression that the tobacco product is less harmful compared to the others;

      12) from self-service shelves;

      13) as part of sets with other products;

      14) in the trade organizations, selling goods for children.

      3. In the places where tobacco products are sold, in a prominent place, an inscription should be placed: "Sale of tobacco products to the persons and by the persons under eighteen years of age shall be prohibited", as well as a warning about the danger of smoking, approved by the Government of the Republic of Kazakhstan.

      4. When selling tobacco products to the persons, whose age, judging by their appearance, is less than eighteen years of age, the persons, selling the tobacco products shall:

      1) require an ID, to know the actual age of the buyer;

      2) refuse to sell tobacco products in case if an ID was not shown.

      5. Smoking shall be prohibited in:

      1) education institutions, and recreation organizations for the minors;

      2) health care organizations;

      3) foodservice outlets;

      4) cinemas, theaters, circuses, concerts, exposition and exhibition halls, sports arenas and other indoor facilities, designed for public recreation, including in night clubs and discos;

      5) museums, libraries and lecture halls;

      6) unestablished places in local and long-distance trains, marine and river vessels;

      6-1) on aircrafts, buses and mini-vans, transporting passengers, taxis and municipal electric transport;

      7) buildings of airports, railway, auto and water stations;

      8) the state bodies and organizations;

      9) the rooms, that are the working places;

      10) porches of houses.

      6. The standards provided for in subparagraphs 3), 6), 7) of paragraph 5 of this Article shall not be applied in the cases if the special smoking areas are allotted.

      7. The places, allotted specifically for smoking, shall be equipped in accordance with the requirements, established by the Government of the Republic of Kazakhstan.

      8. A manufacturer, an importer of tobacco products shall be required annually up to the 1 February of the following year to submit the reports on the results of laboratory tests on maximal permissible content of nicotine and tar in all types of tobacco and tobacco products, on tobacco product ingredients, they released or are planning to produce, sold or distributed during the preceding twelve months in the territory of the Republic of Kazakhstan, in the order, approved by the Government of the Republic of Kazakhstan.

      9. Examination of nicotine, tar and other harmful compounds - systemic poisons, carcinogenic and mutagenic substances in tobacco products shall be performed by a manufacturer, an importer of tobacco products at their own expense in the laboratories, accredited in accordance with the legislation of the Republic of Kazakhstan.

      10. Import, manufacture, sale and distribution of tobacco products, exceeding the maximum permitted levels of containing nicotine and tar, defined by the Government of the Republic of Kazakhstan shall be prohibited.

      11. Manufacturing, sale and distribution of the goods, imitating tobacco products shall be prohibited.

      12. The places, banned for smoking, should have the signs prohibiting smoking.

      13. Pack of tobacco product, packaging of tobacco products shall contain a warning about the dangers of smoking, approved by the Government of the Republic of Kazakhstan shall meet the following requirements that:

      1) take no less than forty percent of every large side ?of a pack of tobacco product, a packaging of tobacco products;

      2) shall not be printed on a transparent wrapping film, or any other outer wrapping material;

      3) should be made in the form of a picture (icon, graphics) and inscriptions.

      14. Sale of alcoholic beverages shall be prohibited:

      1) to the persons under the age of twenty-one years;

      2) on certain days and hours, established by the legislation of the Republic of Kazakhstan on administrative offences;

      3) in other cases, provided by the legislation of the Republic of Kazakhstan.

      Footnote. Article 159, as amended by the Law of the Republic of Kazakhstan dated on 05.07.2011 No 452-IV (shall be enforced from 13.10.2011); dated on 04.07.2013 No 132-V (shall be enforced upon expiration of ten calendar days after its first official publication).

**Article 160. Prevention of iron deficiency**

      1. Iron deficiency anemia - a pathological process of the body, caused by insufficient intake and absorption of iron in the body, the increased iron losses in certain chronic diseases of gastrointestinal, genitourinary systems and the blood system, the increased iron requirements.

      2. The preventive measures for iron deficiency shall be based on the following principles:

      1) liability of state bodies, individuals and legal entities for compliance with the requirements for production, import, export, sale and movement in the other stages of the fortified foods turnover in the Republic of Kazakhstan;

      2) provision of preventive iron-containing medications for the target population groups;

      3) accessibility to health care in healthcare organizations for the persons, suffering from iron deficiency anemia;

      4) fortification of flour and other food products with iron-containing vitamins, minerals and other substances.

      3. Extra and first grade wheat flour, sold in the territory of the Republic of Kazakhstan, shall be subject to mandatory fortification with iron-containing vitamins, minerals and other substances.

      The order of fortification of food shall be defined by the Government of the Republic of Kazakhstan.

**Article 161. Prevention of iodine deficiency disorders**

      1. Prevention of iodine deficiency disorders shall be based on the following principles of:

      1) responsibility of the state bodies, individuals and legal entities for compliance with the requirements for production, import, export, sale of iodized edible and fodder salt in the Republic of Kazakhstan;

      2) accessibility of medical assistance in health care organizations to the persons, suffering from iodine deficiency disorders;

      3) protection of the citizens’ rights in case of loss of health, caused by the harmful effects of iodized salt and other food products, fortified with iodine.

      2. Iodization of edible and fodder salt shall be made in accordance with the legislation of the Republic of Kazakhstan on prevention of iodine deficiency disorders.

 **SECTION 7. DONATION AND TRANSPLANTATION**

 **Chapter 26. DONATION OF BLOOD AND ITS COMPONENTS**

**Article 162. Donation, banking of blood, its components and preparations**

      1. Donation of blood and blood components (hereinafter - the donation) - a voluntary participation of donors in protection of citizens' health by giving (donating) of blood and blood components for medical purposes.

      2. Donation shall include a set of measures on medical examination of a donor, banking of his blood, recovery and storage of blood components.

      3. The process of blood banking and its components shall include:

      1) giving (donating) of blood - a one-time blood taking from a donor;

      2) giving (donating) of plasma - a one-time extraction of blood plasma by plasmaphairesis method.

      Depending on the immune characteristics of the received plasma, there shall be:

      the isoimmune plasma, containing a certain concentration of specific protein structures (isoimmune antibodies), used for production of blood products and diagnostic reagents;

      the immune plasma, containing a certain concentration of specific protein structures (immune antibodies) of natural or synthetic origin, having the property of the targeted therapeutic interaction for certain types of pathogens. The immune plasma shall be used for transfusion to a recipient, or for production of blood products;

      3) giving (donating) cells - a one-time extraction of donor blood cells by cytapheresis method.

      4. In the process of blood banking and processing, the following components shall be received:

      1) blood components – the blood components, derived from it in the form of cells and cell-free medium;

      2) blood products – the medicines, obtained during processing of blood components.

      5. The nomenclature, the rules of banking, processing, storage, sale of blood, its components, and the rules of storage, transfusion of blood, its components, and products shall be approved by the authorized body.

**Article 163. Healthcare and other organizations, working in the field of organ donation, banking of blood, its components and preparations**

      1. Banking, processing, storage and sale of blood and its components shall be carried out by the licensed state healthcare organizations.

      2. Blood products shall be produced by the organizations having a relevant license.

      3. Healthcare and other organizations, working in the field of organ donation, banking of blood, its components and preparations shall be responsible for their quality in the order, defined by the Laws of the Republic of Kazakhstan.

      4. In case of emergency or martial law in the territory of the Republic of Kazakhstan, the donorship shall be organized in accordance with the legislation of the Republic of Kazakhstan.

**Article 164. Ensuring the safety and quality of donor blood, its components and preparations**

      1. Safety of blood and its components shall be achieved by quarantining, virus-inactivation, exposure to radiation and other methods, permitted in the territory of the Republic of Kazakhstan.

      2. The donated blood and its components shall be subject to quality control in the order, specified by the authorized body.

      3. It shall be prohibited to use and sell the donated blood, its components, and preparations without proper labeling.

      4. Healthcare organizations and medical personnel, making transfusion of blood and its components and preparations shall be required to ensure compliance with the requirements for their safe use.

**Article 165. The donor, his rights and obligations**

      1. A donor may be an individual of eighteen years and older, who has completed a medical examination and has no contraindications, who has expressed a desire for voluntary giving (donating) of blood and blood components for medical purposes.

      2. The donor shall have the right to:

      1) give (donate) blood and its components gratuitously;

      2) give (donate) blood and blood components for a fee in the amount, specified by the Government of the Republic of Kazakhstan;

      3) review the results of the medical examination;

      4) be encouraged in compliance with this Code.

      3. The donor must inform about all the existing or previous diseases, as well as about the use of drugs, psychotropic substances and precursors.

**Article 166. Medical examination of the donor**

      1. Before giving (donating) blood and blood components, the donor shall pass a free of charge compulsory medical examination in the order, defined by the authorized body.

      2. Health certificates for implementation of donor functions shall be given in public healthcare institutions for free.

**Article 167. The guarantees, provided to the donor**

      1. During the medical examination and donation of blood and blood components, an employee, who is a donor, shall beliberated from work for the examination with the average salary preserved.

      2. In case if under an agreement with the employer, in the days of donating blood and its components, the employee, who is the donor, shall come to work, at his request, he shall be given another day off with an average salary preserved, or the day may be attached to the annual leave.

      3. In the days of donating blood and blood components, it shall be prohibited to involve the employee to the night work, overtime work, heavy work or work under harmful (particularly harmful) and (or) hazardous working conditions.

      4. A military serviceman who is a donorshall be released from having duties, duty watches and other forms of services in the days of giving (donating) blood and blood components.

      5. The students who are donorsshall be released from the educational process in the days of giving (donating) blood and its components.

      6. The system of encouraging the donors shall be approved by the authorized body.

      Additional incentives, provided to the donor, taking into account the total number of donations of blood and blood components are defined by the legislative acts of the Republic of Kazakhstan.

      7. A donor, donating blood gratuitously, in order to compensate the amount of his blood and energy expenditures of his body after giving (donating) blood and its components, shall have the right to choose a free meal or its cash equivalent in the sum, specified by the Government of the Republic of Kazakhstan.

      8. A donor, donating blood on a fee basis, shall receive the payment in the manner and the amount, established by the Government of the Republic of Kazakhstan from a health care organization, involved in banking of blood and its components.

**Article 168. Responsibilities of employers and leaders of organizations to create conditions for donorship development**

      1. Employers and heads of organizations, in order to create conditions for donorship development shall:

      1) support local state healthcare management bodies, public healthcare organizations to attract people to donorship;

      2) provide the necessary facilities and create conditions for sampling blood and blood components;

      3) give a day off to an employee, who is a donor on the day of medical examination and giving (donating) blood and blood components;

      4) provide the employee, who is the donor, with the guarantees, established by this Code.

      2. Employers and managers of organizations shall have the right to provide extra encouragement of donors.

 **Chapter 27. TRANSPLANTATION OF TISSUES AND (OR) ORGANS (PARTS OF ORGANS)**

**Article 169. Transplantation of tissues and (or) organs (parts of organs) and conditions for donor organ recuperation**

      1. A person, a corpse of a person or an animal may be a donor for transplantation of tissues and (or) organs (parts of organs).

      2. Forced recuperation of tissues and (or) organs (parts of organs) from a person and their transplantation shall be prohibited.

      3. Purchase and sale of tissues and (or) organs (parts of organs) of a person shall be prohibited.

      4. A living donor for transplantation may be a person, who is in a genetic relationship with a recipient and has tissue compatibility with him (the immunological property of organic tissues, contributing to their engraftment to the tissues of another organism).

      5. A living donor must pass a comprehensive medical examination and receive a conclusion of a concilium on the possibility for recuperation of his tissues and (or) organs (parts of organs).

      6. Recuperation of tissues and (or) organs (parts of organs) from a living donor, who is a minor or a legally incapable person, shall be possible only under simultaneous observance of the following conditions, along with those specified in this article:

      1) a written notarized consent of his legal representatives, who have received the necessary information about the health status, in accordance with Article 91 of this Code;

      2) absence of another related donor who is able to give relevant consent;

      3) the recipient is a brother or a sister of the donor;

      4) transplantation is intended to save the life of the recipient;

      5) the potential donor does not reject a donor organ recuperation.

      7. The consent of the legal representatives of minors or legally incapable persons may be revoked any time before medical intervention.

      8. Recuperation of tissues and (or) organs (parts of organs) from a living donor may be performed only with his written notarized consent.

      9. One of the paired organs, a part of an organ or tissue only, the absence of which would not entail irreversible health problems may be recuperated for transplantation.

      10. Recuperation of tissues and (or) organs (parts of organs) of a corpse shall not be allowed if at the time of recuperation the healthcare organization shall be informed that during the life of the person or his or her spouse (wife), the close relatives or legal representative were against recuperation of his tissues and (or) organs (parts of organs) after the death for transplantation.

      Tissues and (or) organs (parts of organs) may be recuperated from a corpse for transplantation, if there is clear evidence of the death, recorded by a concilium.

      Certification of death shall be given on the basis of pronouncement of biological death or irreversible brain death in the order, established by the authorized body.

      11. The persons, involved in recuperating of tissues and (or) organs (parts of organs) for subsequent transplantation shall not be allowed for participation in pronouncement of biological death or irreversible brain death.

**Article 170. The procedure for transplantation of tissues and (or) organs (parts of organs)**

      1. A medical conclusion on the need of tissue and (or) organ (parts of organs) transplantation shall be given by a concilium of the relevant health care organization.

      2. Transplantation of tissues and (or) organs (parts of organs) shall be performed with the written consent of a recipient or a legal representative of a minor recipient or a recipient, recognized incapable by the court.

      3. A recipient or a legal representative of a minor recipient or a recipient, recognized incapable by the court, shall be warned about the possible complications to the recipient’s health in connection with the upcoming transplant surgery.

      4. Transplantation of infected tissues and (or) organs (parts of organs) shall be prohibited.

      5. Recuperation and preservation of tissues and (or) organs (parts of organs) from a living donor shall be performed only in public healthcare organizations and health organizations with the state participation, as well as in the National Healthcare holding and its subsidiaries, engaged in "Transplantation" activity in accordance with the license.

      6. Recuperation and preservation of tissues and (or) organs (parts of organs) from the corpses for transplantation shall be performed in public healthcare organizations and the health organizations with the state participation, as well as in the National Healthcare holding and its subsidiaries.

      7. Transplantation of tissues and (or) organs (parts of organs) shall be allowed only in public healthcare organizations and in the healthcare organizations with the state participation, as well as in the National Healthcare holding and its subsidiaries, engaged in "transplantation" activity in accordance with the license.

      8. The procedure and conditions for recuperation, preservation, transplantation of tissues and (or) organs (parts of organs) from a person to a person and from animals to humans shall be specified by the authorized body.

      9. This Article shall not be applied to the tissues and (or) organs (parts of organs), related to human reproduction process, including reproduction tissues (reproductive cells), as well as to blood and its components.

      Footnote. Article 170, as amended by the Law of the Republic of Kazakhstan, dated on 19.01.2011 No 395-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 171. The rights of a donor and a recipient**

      1. A donor, in addition to the rights provided for in Article 165 of this Code, shall have the right:

      1) to receive the complete information about the possible complications to his health in connection with the upcoming recuperation of tissues and (or) organs (parts of organs) from the health care organizations;

      2) to receive treatment, including medication, in the health care organization in connection with the recuperation of tissues and (or) organs (parts of organs) within the frames of the guaranteed volume of free medical care.

      2. The recipient shall have the right:

      1) to demand complete information about the possible complications to his health for the upcoming transplantation of tissues and (or) organs (parts of organs) from the health care organizations;

      2) to receive treatment, including medication, in the health care organization in connection with the surgical intervention within the frames of the guaranteed volume of free medical care.

      3. Medical and other employees of health care organizations shall be prohibited to disclose information about a donor and a recipient.

 **Chapter 28. IMPORT, EXPORT OF HUMAN TISSUES AND (OR) ORGANS (PARTS OF ORGANS), HEMATOPOIETIC STEM CELLS, BONE MARROW, BLOOD AND ITS COMPONENTS, SAMPLES OF CELLS, TISSUES, BIOLOGICAL FLUIDS AND HUMAN SECRETIONS**

      Footnote. The title of Article 28 is in the wording of the Law of the Republic of Kazakhstan dated on 21.06.2013 No 107-V (shall be enforced upon expiration of thirty calendar days after its first official publication).

**Article 172. Grounds for import, export of organs (parts of organs)and (or)human tissues, hematopoietic stem cells, bone marrow of a human being**

      1. Importation of organs (parts of organs) and (or) human tissues, hematopoietic stem cells, bone marrow of a human being to the territory of the Republic of Kazakhstan shall be performed for:

      1) transplantation in public healthcare organizations;

      2) diagnostic studies in the territory of the Republic of Kazakhstan;

      3) joint scientific researches.

      2. Export of organs (parts of organs) and (or) human tissues, hematopoietic stem cells, bone marrow of a human being from the Republic of Kazakhstan shall be performed for:

      1) providing medical assistance to the citizen of the Republic of Kazakhstan, located abroad;

      2) providing medical assistance to the close relatives and spouses of the citizens of the Republic of Kazakhstan, who are located out of the Republic of Kazakhstan;

      3) diagnostic researches;

      4) joint scientific researches;

      5) in the cases, provided for in international treaties, ratified by the Republic of Kazakhstan.

      6) transplantation of hematopoietic stem cells, bone marrow of a human being from a donor, residing in the territory of the Republic of Kazakhstan to a recipient, residing abroad.

      3. Alisencefor import to the territory of the Republic of Kazakhstan from the countries that are not the members of the Customs Union, and export from the territory of the Republic of Kazakhstan to the countries of human tissues and (or) organs (parts of organs) in the cases, provided for in subparagraph 1) of paragraph 1 and sub-paragraphs 1), 2) and 5) of paragraph 2 of this Article shall be issued by the authorized body at the request of the healthcare organizations, engaged in "transplantation", “haematology” activities in accordance with the license for medical services.

      4. Import and export of hematopoietic stem cells, bone marrow of a human being from and to the territory of the Republic of Kazakhstan shall be performed for unrelated transplantation under the resolution (permission), issued by the authorized body.

      5. Import and export of organs and (or) human tissues by individuals shall be prohibited.

      6. The order of examination for biological safety, conservation and transportation of human tissues and (or) organs (parts of organs), intended for import and export, shall be defined by the authorized body.

      Footnote: Article 172 is in the wording of the Law of the Republic of Kazakhstan dated on 21.06.2013 No. 107-V (shall be enforced upon expiration of thirty calendar days after its first official publication).

**Article 173. Grounds for import, export of blood and blood components, samples of cells, tissues, biological fluids and human secretions**

      Footnote. The title of Article 173 is in the wording of the Law of the Republic of Kazakhstan dated on 21.06.2013 No. 107-V (shall be enforced upon expiration of thirty calendar days after its first official publication).

      1. Import of blood and blood components to the territory of the Republic of Kazakhstan shall be performed for:

      1) providing medical assistance in the territory of the Republic of Kazakhstan;

      2) diagnostic studies in the territory of the Republic of Kazakhstan;

      3) joint scientific researches.

      2. Export of blood and blood components from the Republic of Kazakhstan shall be performed for:

      1) providing medical assistance to the citizen of the Republic of Kazakhstan, located abroad;

      2) providing medical assistance to close relatives and spouses of citizens of the Republic of Kazakhstan, who are outside the Republic of Kazakhstan;

      3) diagnostic researches;

      4) joint scientific researches;

      5) in the cases, provided for in international treaties, ratified by the Republic of Kazakhstan.

      6) when sending blood components abroad for production of plasma blood preparations at the plants of foreign producers from the blood components, banked at the state healthcare organizations, engaged in blood banking services of the Republic of Kazakhstan, in order to provide Kazakhstan population with blood preparations (contract fractionation).

      3. Apart from the cases, provided for in paragraphs 1 and 2 of this Article, the import and export of blood and its components may be performed by way of exchange. This exchange shall be carried out only in the cases when the blood and its components with the required biological properties shall be not available.

      4. Permission for import and exportof blood and blood components fromand to the territory of the Republic of Kazakhstan from the countries that are not the member states of the Customs Union, in the cases, provided in subparagraph 1) of paragraph 1 and sub-paragraphs 1), 2) and 5) of paragraph 2 of this Article, shall be issued by the authorized body at the request of the healthcare organizations, engaged in blood banking activity in accordance with the license.

      5. Import and export of samples of cells, tissues, body fluids and secretions, including the products of human activity, physiological and pathological secretions, smears, scrapings, swabs, intended for diagnostic and research purposes, or received during biomedical research, shall be performed under the resolution (permission), issued by the authorized body.

      6. Import and export of blood and its components by individuals shall be prohibited.

      Footnote. Article 173 as amended by the Law of the Republic of Kazakhstan dated on 21.06.2013 No. 107-V (shall be enforced upon expiration of thirty calendar days after its first official publication).

**Article 174. The order of import, export of human tissues and (or) organs (parts of organs), blood and blood components**

      1. Import and export of organs (parts of organs), and (or) human tissues, blood and its components from and to the territory of the Republic of Kazakhstan from and to the countries that are not the member states of the Customs Union by the healthcare organizations, specified in paragraph 3 of Article 172 and paragraph 4 of Article 173 of this Code, shall be performed of the basis of a license, issued in the order, defined by the international agreements on licensing of foreign trade, ratified by the Republic of Kazakhstan and the Law of the Republic of Kazakhstan “On licensing”.

      2. Within three working days, the authorized body shall make a decision on issuance or rejection to issue a license for import and export of human tissues, blood and its components, and within one working day – for import and export of human organs.

      Footnote. Article 174 is in the wording of the Law of the Republic of Kazakhstan dated on 21.06.2013 No. 107-V (shall be enforced upon expiration of thirty calendar days after its first official publication).

 **SECTION 8. EDUCATIONAL AND SCIENTIFIC ACTIVITY IN HEALTHCARE AREA**

 **Chapter 29. EDUCATIONAL ACTIVITIES IN HEALTHCARE**

**Article 175. Educational activities in healthcare**

      1. The educational goals in healthcare shall be the professional training of the teaching, medical and pharmaceutical personnel for the healthcare system, their training and retraining.

      2. Educational activities in health care shall be conducted in the organizations of medical and pharmaceutical education and at the medical and pharmaceutical faculties of education organizations, implementing the programs for technical and vocational education, post-secondary, higher, postgraduate and supplementary education in accordance with the legislation of the Republic of Kazakhstan in education area. A mandatory condition for implementation of the programs for medical education shall be the availability of clinical sites - clinical departments of medical education organizations, as well as the healthcare organizations, providing relevant conditions for training of medical and pharmaceutical personnel under the contracts with the medical education organizations.

      3. The state compulsory standards and standard professional training programs for medical and pharmaceutical specialties, and a regulation on clinical sites of higher medical institutions and the requirements to them shall be approved by the authorized body.

      4. For those, who have mastered the educational programs of technical and vocational education, post-secondary, higher, postgraduate and supplementary education, the ground for their employment in health care organizations shall be the education certificate in the government-approved format, and a specialist certificate for the clinical specialties.

      5. Post-graduate medical and pharmaceutical education includes residency, master and doctoral studies. The regulation on residency shall be approved by the authorized body.

      6. Supplementary education shall be provided in medical institutions of education and science, implementing educational training programs for supplementary education.

      The main forms of supplementary education are the career development and retraining of medical and pharmaceutical personnel. The order of career development and retraining of medical and pharmaceutical personnel shall be defined by the authorized body.

      7. Training of medical and pharmaceutical personnel shall be performed by the authorized body, as well as by the local public healthcare management bodies within their powers, taking into account the needs of the branch.

**Article 176. Qualification examinations for healthcare professionals**

      1. Qualification examinations for healthcare professionals shall be conducted in order to assess readiness of those with secondary (technical and vocational), post-secondary, higher medical education, for the medical activities.

      2. Qualification examinations for healthcare professionals shall be divided into:

      1) mandatory - to assess compliance of the medical personnel of clinical specialty and their admission to clinical practice (working with patients) with issuance of a relevant specialist certificate;

      2) voluntary - to assess professional level with assigning of an appropriate qualification category.

      3. An individual without an appropriate specialist certificate, as well as those with the expired certificate shall not be allowed for clinical practice.

      4. The order and timing of qualification examinations for healthcare professionals shall be be defined by the authorized body.

      5. The procedure and conditions for access to the qualification examinations for healthcare professionals, who have passed medical training and received qualification categories outside of the Republic of Kazakhstan, shall be defined by the authorized body.

      6. The document, entitling to engage in medical practice or certifying assignment of a qualifying category, received by the specialists in other countries, invited to work in the National Healthcare Holding and its subsidiaries, as well as in the "Nazarbayev University" or its medical organizations shall be equal to the specialist certificate without assigning a category, operating in the Republic of Kazakhstan.

      Footnote. Article 176, as amended by the Law of the Republic of Kazakhstan, dated on 19.01.2011 No 395-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 177. Oath of a doctor of the Republic of Kazakhstan**

      Graduates of higher education institutions, who passed training in medical specialties, take the oath of a physician of the Republic of Kazakhstan as follows: "Taking the high title of a doctor, in the face of my teachers and colleagues, I solemnly swear to serve faithfully and loyally to the medicine, fully devoting myself to protection of public health. In my work I swear to be guided only by the interests of the patients, whose health is the supreme value. I swear to provide medical care with equal eagerness and patience to everyone who needs it, regardless of age, gender, nationality, religion, social status or nationality. I swear to keep medical secrets, never use it for personal profit. I swear to improve constantly my knowledge and skills, to be demanding to myself and my disciples, never refuse to provide generous assistance and seek advice from colleagues if the patient’s interests require it. I swear to protect and increase the noble traditions of Kazakhstan medicine, and thank and respect those who taught me the healing art".

 **Chapter 30. SCIENCE IN HEALTHCARE**

**Article 178. Subjects of scientific research in healthcare**

      1. A scientific organization in healthcare (hereinafter - the research organization) - a legal entity, engaged in scientific and (or) scientific and technical activities, training of scientific personnel in healthcare area.

      2. Scientific organizations shall be divided into research organizations (research institutes, research centers), higher medical and pharmaceutical education organizations and other organizations, engaged in scientific activities.

      3. Scientific organizations may be engaged in medical, pharmaceutical and educational activities in accordance with the legislation of the Republic of Kazakhstan in education and healthcare areas.

**Article 179. Coordination of scientific research activities in healthcare**

      1. Priorities of scientific research of fundamental and applied nature, coordination of scientific support in healthcare, a concept of medical science shall be developed by the authorized body.

      2. The authorized body shall be the founder of scientific organizations.

      3. The authorized body shall perform a scientific and medical expertise of scientific programs in healthcare.

**Article 180. Medico-biological experiments, pre-clinical (non-clinical) and clinical researches, application of new techniques of diagnosis, treatment and medical rehabilitation**

      1. The purpose of the medical and biological experiments, pre-clinical (non-clinical) and clinical studies shall be the assessment and receipt of evidence of their safety and effectiveness via scientific methods.

      2. Pre-clinical (non-clinical) studies shall be made on animals.

      3. Clinical research involving people (patients or volunteers), provided that the positive results of pre-clinical (non-clinical) studies were obtained, may be conducted only with the written informed consent.

      4. Clinical studies involving minors may be conducted in parallel with the persons, who reached the age of majority, in order to obtain the data on:

      1) medical technology or pharmaceuticals for healing of children;

      2) the best dosage of the drug for treatment of minors.

      Clinical tests involving minors shall be conducted only with the written informed consent of their legal representatives.

      5. Upon receipt of a consent to participate in a clinical test, a legal representative of a minor, a patient or a volunteer shall be be informed about:

      1) the medical technology, pharmaceuticals or drug, the nature and duration of the clinical test;

      2) the safety and efficacy of medical technology, pharmaceutical of drug, as well the risk to the health;

      3) the actions in case of unforeseen effects of the use of medical technology, pharmaceuticals, drugs to the health status;

      4) the terms of health insurance.

      6. Clinical tests shall be terminated at any stage:

      1) at the request of a minor, his legal representative, a patient or a volunteer, participating in the test;

      2) in case of a threat to life and health of a minor, a patient or a volunteer.

      7. The mandatory requirements for conducting clinical tests shall be the official registration of documents on life and health insurance of patients and volunteers, involved in the tests, as well as the ethical assessment of research materials.

      8. The use of new methods of diagnosis, treatment and medical rehabilitation shall be possible if positive results of clinical tests were received.

      9. Conduction of clinical tests of medical technology, pharmaceuticals and medical products shall be prohibited on:

      1) the minors, who do not have legal representatives;

      2) pregnant women, except for the cases, when the clinically tested medical technologies and medicines are intended for pregnant women, and the necessary information may only be obtained in clinical tests with participation of pregnant women and when the risk of harm to the pregnant woman and the fetus is fully eliminated;

      3) the military servicemen;

      4) the persons, serving sentences in prison, and the persons, kept in temporary detention facility and in detention centers;

      5) the persons, recognized incapable by the court, except for the clinical tests of medical technologies and medicines, intended for treatment of mental disorders (diseases), for the patients with mental disorders (diseases).

      10. Standards for conducting clinical tests (proper clinical practice and research) shall be approved by the authorized body and the state bodies within their competence.

      11. The order of conducting biomedical experiments, pre-clinical (non-clinical) and clinical research, as well as the application of new methods, diagnostics, treatment and medical rehabilitation shall be approved by the authorized body.

      12. Issuance of permits for non-clinical (non-clinical) and clinical test of pharmaceutical and drugs, as well as clinical testing of medical technologies shall be carried out by the authorized body.

      13.

Is excluded by the Law of the Republic of Kazakhstan, dated on 10.07.2012 No 36-V (shall be enforced upon expiration often calendar days after its first official publication.)

      Footnote. Article 180, as amended by the Law of the Republic of Kazakhstan, dated on 10.07.2012 No. 36-V (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 181. Ethics Commissions**

      1. Ethics Commissions shall be the independent expert bodies, protecting the rights, safety and welfare of the researched people and the researchers, as well as moral, ethical and legal assessment of the clinical test materials.

      2. The purpose of the Ethics Commissions shall be to protect the rights and dignity of a person in relation to the application of biology and medicine achievements.

      3. The tasks of the Ethics Commissions shall be to:

      1) conduct an independent review of the research documents;

      2) conduct an independent evaluation of safety and observance of human rights in the phase of planning and performing the test;

      3) assess compliance of the clinical research program with the standards of proper clinical practice and research, as well as qualification of researchers and technical equipment of a healthcare organization, conducting the test;

      4) assess observance of the international and national ethical standards when conducting clinical tests;

      5) participate in development of documents on biological and medical ethics.

      4. The ethics commissions may include experts in the areas of health, science, art, law, religious confessions and public associations.

      5. The Central and local Ethics Commissions shall be establishedIn the Republic of Kazakhstan.

      6. The Central Ethics Commission shall be established under the authorized body for independent evaluation of tests, conducted at the international and national levels.

      The structure and the regulation on the Central Ethics Commission shall be approved by the authorized body.

      7. Local Ethics Commissions shall be established under the healthcare organizations for independent evaluation of researches, conducted on the basis of these organizations.

      The structure and the regulation on the local Ethics Commission shall be approved by the order of the head of the health care organization, where the commission shall be established.

 **SECTION 9. LEGAL STATUS, SOCIAL PROTECTION OF MEDICAL AND PHARMACEUTICAL SPECIALISTS**

 **Chapter 31. RIGHTS AND DUTIES, LABOR RELATIONS, THE CODE OF HONOR FOR MEDICAL AND PHARMACEUTICAL SPECIALISTS**

**Article 182. Rights and responsibilities of medical and pharmaceutical specialists**

      1. Medical and pharmaceutical specialists shall be entitled to:

      1) have necessary conditions for their professional activity;

      2) perform private medical practice and pharmaceutical services;

      3) improve their qualification level at the expense of budget funds or the employer if they work in private health care organizations not less than once every five years;

      4) pass retraining at the expense of budget funds or the employer in case of layoffs due to downsizing or liquidation of the state healthcare organizations;

      5) receive compensation for the harm, caused to life or health in connection with performance of labor (official) duties;

      6) have smooth and free access to communication facilities, belonging to the organizations or citizens, as well as any available form of vehicle to transport a citizen to the nearest medical institution in the cases, threatening to his life;

      7) receive service housing;

      8) receive reimbursement of travel costs, associated with the itinerant nature of work;

      9) be rewarded for their professional duties at a high qualitative level;

      10) receive protection of their professional honor and dignity;

      11) have professional liability insurance for damage to the health of citizens in the absence of negligence or neglect by healthcare professional.

      2. Training and retraining of the teaching staff of public healthcare organizations shall be carried out at the expense of budget funds, the employer's funds, own funds, as well as at the expense of other non-prohibited sources.

      3. Medical and pharmaceutical specialists of the state healthcare sector, working in rural areas and small towns, shall be provided with the additional social support:

      1) a fringe benefit to the basic salary in the amount, defined by the local representative bodies;

      2) compensation of costs for utilities services and fuel at the expense of budget funds in the amount, set by the local representative bodies of the regions, town of republican significance and the capital;

      3) those, who have livestock in private ownership are provided with fodder, land plots for grazing and hay-making upon the decision of local representative and executive bodies;

      4) in addition to the benefits, provided by the laws of the Republic of Kazakhstan, the healthcare professionals can receive additional benefits at the expense of local budgets, the amounts of which are defined by local representative bodies.

      4. Medical and pharmaceutical specialists of state healthcare organizations, working in rural areas shall be provided with additional social support, prescribed by the Law of the Republic of Kazakhstan "On State Regulation of development of agriculture sector and rural areas".

      5. Infection with HIV of medical and pharmaceutical staff of healthcare organizations, working with the HIV infected materials, when performing their official and professional duties shall be related to the occupational diseases.

      These persons, for the period of temporary disability due to the occupational disease, shall receive a social allowance for temporary disability in accordance with the labor legislation of the Republic of Kazakhstan.

      Medical and other personnel, the official duties of whom may lead to occupational AIDS disease, shall be subject to compulsory social insurance.

      Health care specialists, employees and technical staff, and those, involved directly in preventive, therapeutic and diagnostic and research work, related to HIV / AIDS, shall have a right to a six-hour working day, additional paid leave of twenty-four calendar days, additional payment for professional harm at the rate of sixty per cent of the set wage.

      6. Medical and pharmaceutical workers shall have to:

      1) perform their professional duties, respect and humanely treat their patients, and be guided by the principles of medical ethics and deontology properly;

      2) promote prevention of disease and improvement of health, provide medical care;

      3) provide emergency medical assistance to the population in case of emergency;

      4) promote health knowledge and healthy lifestyles among the population;

      5) comply with the Code of Honor of medical and pharmaceutical workers, keep patient confidentiality, not to disclose information about diseases, private and family life of citizens;

      6) continuously develop and improve their professional skills;

      7) involve other specialists or those with higher qualifications for consultations if necessary.

      7. Interference of the state bodies and officials, as well as the citizens in professional activities of medical and pharmaceutical workers shall be prohibited, except for the cases, provided herein.

      8. When performing their professional duties, the medical and pharmaceutical workers shall not be allowed to conduct any actions (inactions) under their religious beliefs, as well as conduction of religious rites and ceremonies, which may cause damage to life and health of individuals.

      Footnote. Article 182, as amended by the Law of the Republic of Kazakhstan, dated on 11.10.2011 No 484-IV (shall be enforced upon expiration of ten calendar days after its first official publication.)

**Article 183. Labor relations of workers of health care organizations**

      1. Labor relations of workers of health care organizations shall be regulated by the labor legislation of the Republic of Kazakhstan.

      2. Payment for the labor of employees in public healthcare organizations shall be made in the order, defined by the labor legislation of the Republic of Kazakhstan.

      3. Appointment and dismissal of the heads of subordinate organizations and their deputies, including the institutions of education and science shall be conducted by the authorized body.

**Article 184. The Code of Honor of medical and pharmaceutical workers of the Republic of Kazakhstan**

      1. The Code of Honor of medical and pharmaceutical workers of the Republic of Kazakhstan (hereinafter - the Code of Honor) shall define the moral responsibility of the medical and pharmaceutical workers for their activities to the citizens and society as a whole.

      2. In their work the medical and pharmaceutical workers shall:

      1) be guided by this Code and the Code of Honor;

      2) help improve the health of citizens of the Republic of Kazakhstan;

      3) take decisions solely in the interests of the patient;

      4) prevent commissioning of acts which may discredit the high title of the medical and pharmaceutical worker of the Republic of Kazakhstan;

      5) perform their duties conscientiously and efficiently;

      6) improve their professional knowledge continuously;

      7) prevent promotion and use of methods and means of prevention and treatment, for their personal profit;

      8) observe strictly the labor discipline;

      9) preserve and take good care of the property of healthcare organizations;

      10) fight corruption;

      11) not allow to use confidential information for financial gain or other personal profit;

      12) promote sustainable and positive moral and psychological climate in the team;

      13) prevent and suppress violations of the norms of the Code of Honor by other medical and pharmaceutical workers;

      14) comply with the established form of clothing during performing their official duties.

      3. In relations with the patients, the medical and pharmaceutical workers shall have to:

      1) respect the rights and dignity of all persons, regardless of age, gender, nationality, religion, nationality, origin, social and property status, or any other circumstances;

      2) provide medical care to everyone who needs it;

      3) constantly remember their duty to preserve human life;

      4) enhance public confidence in the state healthcare system;

      5) prevent fraud and other extortions against patients, make efforts to suppress such actions on the part of their colleagues;

      6) by their actions, not give rise to justified criticism from society, to tolerate it, use constructive criticism to correct deficiencies and improve their professional activities.

      4. In relations with the colleagues, the medical and pharmaceutical workers shall have to:

      1) observe generally the accepted ethical standards, be polite and correct;

      2) provide generous support and seek advice from colleagues if the patient’s interests required it;

      3) not question publicly the professional qualifications of other medical and pharmaceutical worker;

      4) multiply the traditions and achievements of Kazakhstan's medicine.

      5. Observance of the Code of Honor by the medical and pharmaceutical workers is their professional duty.

      6. A healthcare organization, upon a decision of its head, may consider non-observance of the Code of Honor by the medical and pharmaceutical worker and make a public reprimand upon the consideration results.

      7. The heads of health care organizations provide placement of the text of the Code of Honor for visual propaganda.

 **SECTION 9-1. Basic provisions of the national preventive mechanism**

      Footnote. The Code shall be supplemented by the Section 9-1 in accordance with the Law of the Republic of Kazakhstan dated on 02.07.2013 No. 111-V (shall be enforced upon expiration pf ten calendar days after its first official publication).

 **Chapter 31-1. The National preventive mechanism**

**Article 184-1. The National preventive mechanism**

      1.The National preventive mechanism shall be in the form of the system preventing tortures and other cruel, inhuman or degrading treatment or punishment, functioning through the work of participants of the national preventive mechanism.

      2. As part of its activities, the members of the national preventive mechanism shall visitorganizations for compulsory treatment (specialized anti-TB organizations, drug addiction treatment organizations for compulsory treatment, psychiatric hospitals for application of compulsory medical measures (a psychiatric hospital of a general type for compulsory treatment, a specialized psychiatric hospital, a specialized psychiatric hospital with intensive supervision) and other organizations, defined by the Laws of the Republic of Kazakhstan to be visited by these participants (hereinafter –the preventive visits).

      3. Participants of the national preventive mechanism shall be the Commissioner for Human Rights, as well as the members of public monitoring commissions and associations, selected by the Coordinating Council and engaged in protection of the rights and interests of citizens, lawyers, social workers and doctors.

      4. Human Rights Commissioner shallcoordinate the activities of the participants in the national preventive mechanism, and in accordance with the Laws of the Republic of Kazakhstan shall take measures to ensure the necessary capacity and professional skills of participants of the national preventive mechanism.

      5. Reimbursement of expenditures to the members of the national preventive mechanism for preventive visits shall be covered by the budget in the order, established by the Government of the Republic of Kazakhstan.

**Article 184-2. The Coordinating Council**

      1. In order to ensure effective coordination of the work of the national preventive mechanism under the Commissioner for Human Rights, the Coordinating Council shall be established.

      Members of the Coordinating Council, except for the Ombudsman, shall be elected by the commission, created by the Human Rights Ombudsman, from the citizens of the Republic of Kazakhstan.

      2. Commissioner for Human Rights shall approve:

      the regulation on the Coordinating Council under the Commissioner for Human Rights;

      the procedures for selecting the participants of the national preventive mechanism;

      the procedure for formation of groups of participants of the national preventive mechanism for preventive visits;

      recommendations for preventive visits;

      the procedure for preparation of a consolidated on annual report on preventive visits.

      3. The Coordinating Council shall interact with the Subcommittee on Prevention of Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment of the United Nations Committee against Torture.

**Article 184-3. Requirements for participants of the national preventive mechanism**

      1. Participants of the national preventive mechanism may not be the persons that:

      1) have the unexpunged or unspent convictions;

      2) are suspected or accused of committing a crime;

      3) recognized incapable or partially capable by the court;

      4) judges, lawyers, civil servants and military personnel, as well as the officials of law enforcement and special state bodies;

      5) are registered by a psychiatrist and (or) a narcologist.

      2. The persons who are exempt from criminal liability for non-rehabilitating grounds for committing an intentional crime; dismissed from state or military service, law enforcement and special state bodies, courts or excluded from the Bar for negative reasons, deprived license to practice advocacymay not be the participants of the national preventive mechanism.

**Article 184-4. Rights of a participant of the national preventivemechanism**

      1. A member of the national preventive mechanism shall be entitled to:

      1 ) obtain information about the number of persons, detained in institutions subject to preventive visits, the number of such organizations and their location;

      2) have access to information relating to the treatment of detainees, kept in organizations subject to preventive visits, as well as their conditions of detention;

      3) carry out preventive visits in the prescribed manner in the formed groups;

      4) have talks with persons detained in institutions subject to preventive visits, and (or) their legal representatives, without witnesses, either personally or through an interpreter if necessary, as well as any other person who in the opinion of members of the national preventive mechanism may provide relevant information;

      5) choose and visit organizations subject to preventive visits;

      6) accept reports and complaints of torture and other cruel, inhuman or degrading treatment or punishment.

      2. A member of the national preventive mechanism shall be independent in carrying out lawful activities.

**Article184-5. Responsibilities of participants in the national preventive mechanism**

      1. When exercising their powers, the participants of the national preventive mechanism must observe the legislation of the Republic of Kazakhstan.

      2. Intervention of participants of the national preventive mechanism in the work of entities subject to preventive visits shall be prohibited.

      3. If there are circumstances doubting impartiality of a member of the national preventive mechanism in the group on preventive visits, he must refuse to participate in preventive visits.

      4. Participants of the national preventive mechanism shall register the received reports and complaints of torture and other cruel, inhuman or degrading treatment or punishment in the manner, defined by the Commissioner for Human Rights.

      The received messages and complaints shall be submitted to the Ombudsman in the order, defined by the legislation of the Republic of Kazakhstan.

      Information about the received and submitted reports and complaints shall be included in the report upon the results of preventive visits.

      5. Participants of the national preventive mechanism that violated the provisions of this Code shall be liable under the Laws of the Republic of Kazakhstan.

**Article 184-6. Termination of the powers of the national preventive mechanism**

      Powers of a member of the national preventive mechanism shall terminate for:

      1) violation of the provisions of this Code;

      2) a written statement of resignation;

      3) his death or the entry into force of the court decision declaring him dead;

      4) departure for permanent residence outside the Republic of Kazakhstan;

      5) loss of citizenship of the Republic of Kazakhstan;

      6 ) the entry into force of a judgment of conviction;

      7) occurrence of other cases, stipulated by theLaws of the Republic of Kazakhstan.

**Article 184-7. Types and frequency of preventive visits**

      1. Preventive visits of the members of the national preventive mechanism shall be divided into:

      1) periodic preventive visits, conducted on a regular basis at least once every four years;

      2) intermediate preventive visits conducted between periodic preventive visits to monitor implementation of the recommendations upon the results of the previous periodic preventive visit, as well as to prevent persecution of persons with whom the participants of the national preventive mechanism had talks, by the administrations of the organizations, subject to preventive visits;

      3) special preventive visits, conducted on the basis of the received reports about torture and other cruel, inhuman or degrading treatment or punishment.

      2. The Coordinating Council shall determine the date and the list of organizations, subject to preventive visits, within the allocated budget.

**Article 184-8. The order of preventive visits**

      1. Preventive visits shall be made by the groups, formed by the Coordinating Council from the participants of the national preventive mechanism, in accordance with the rules, approved by the Government of the Republic of Kazakhstan in coordination with the Commissioner for Human Rights.

      2. When forming groups for preventive visits, none of the members of the national preventive mechanism shall be subjected to any discrimination for reasons of origin, social and property status, sex, race, nationality, language, attitude to religion, convictions, place of residence or for any other circumstances.

      3. Administrations of organizations, subject to preventive visits, shall ensure safety of participants of the national preventive mechanism. In the case of wrongful acts of the participants of the national preventive mechanism, the head of the administration of the organizations, subject to preventive visits, shall made a written report to the Commissioner for Human Rights.

      4. After each preventive visit on behalf of the group, a written report shall be made in a form approved by the Coordinating Council, which shall be signed by all members of the group, which has carried out the preventive visits. A member of the group having a dissenting opinion shall write it and attach to the report.

**Article 184-9. Consolidated on annual report of the participants of the national preventive mechanism**

      1. The Coordinating Council shall prepare an annual consolidated on report of the participants of the national preventive mechanism in accordance with their reports upon the results of preventive visits.

      2. The consolidated on annual report of the participants of the national preventive mechanism shall include:

      Recommendations for the authorized state bodies for improvement of conditions for treatment of persons, detained in institutions, subject to preventive visits, and prevention of torture and other cruel, inhuman or degrading treatment or punishment;

      proposals for improving the legislation of the Republic of Kazakhstan.

      The annual consolidated on report of the participants of the national preventive mechanism shall be attached with the financial report for preventive visits, conducted in the past year.

      3. The consolidated on annual report of the participants of the national preventive mechanism shall be sent for consideration to the authorized state bodies and shall be posted on the Internet site of the Ombudsman no later than one month from the date of its approval by the Coordinating Council.

**Article 184-10. Privacy**

      1. Participants of the national preventive mechanism shall not disclose any information about the private life of individuals that have become known to them during preventive visits, without the consent of that person.

      2. Disclosure of information by the participants of the national preventive mechanism about the private life of a person that became known to them during preventive visits, without the consent of the person, shall entail responsibility, established by the Laws of the Republic of Kazakhstan.

**Article 184-11. Interaction of the authorized state bodies with the members of the national preventive mechanism**

      1. The state bodies and their officials shall assist participants of the national preventive mechanism in implementing their legitimate activities.

      None state body or official shall be entitled to restrict the rights and freedoms of citizens for informing the participants of the national preventive mechanism about tortures and other cruel, inhuman or degrading treatment or punishment.

      The officials, hampering the legitimate activities of the participants of the national preventive mechanism, shall be liable under the Laws of the Republic of Kazakhstan.

      2. The authorized state bodies, within three months from the date of receipt of the consolidated on annual report of the participants of the national preventive mechanism, in a written form, shall inform the Commissioner for Human Rights on the measures taken after considering the received reports.

      3. Based on the reports of the participants of the national preventive mechanism on the results of preventive visits, in accordance with the legislation of the Republic of Kazakhstan,the Commissioner for Human Rights shall have the right to appeal to the authorized state bodies or officials with a request to initiate disciplinary, administrative or criminal proceedings against the officer that violated the rights and freedoms of a citizen.

 **SECTION 10. FINAL AND TRANSITIONAL PROVISIONS**

 **Chapter 32. RESPONSIBILITY FOR VIOLATION OF THE LEGISLATION OF THE REPUBLIC OF KAZAKHSTAN IN HEALTHCARE AND THE ORDER FOR ENACTMENT OF THIS CODE**

**Article 185. Responsibility for violation of the legislation of the Republic of Kazakhstan in healthcare**

      Violation of the healthcare legislation of the Republic of Kazakhstan shall entail liability in compliance with the Laws of the Republic of Kazakhstan.

**Article 186. The order of enactment of this Code**

      1. This Code shall be enforced upon expiration of ten calendar days after its first official publication, except for the subparagraphs 8), 10), 11) of paragraph 2 and paragraph 13 of Article 159, which shall beenforcedupon expiration of twelve months after the date of enactment of this Code.

      2. The following Laws of the Republic of Kazakhstan shall be declared repealed:

      1) The Law of the Republic of Kazakhstan dated on October 5, 1994 "On prevention and treatment of the HIV and AIDS" (the Bulletin of the Supreme Council of the Republic of Kazakhstan, 1994, No. 16-17, Art. 212; the Bulletin of the Parliament of the Republic of Kazakhstan, 1999, No. 23, Art. 921, 2004, No. 23, Art. 142, 2006, No. 15, Art. 93, 2007, No. 5-6, Art. 40; No. 9, Art. 67);

      2) The Law of the Republic of Kazakhstan,dated on April 1, 1997 "On Psychiatric Care and the Guarantees of the citizens’ rights when providing such care" (the Bulletin of the Parliament of the Republic of Kazakhstan, 1997, No. 8, Art. 86, 2001, No. 17-18, Art. 245, 2004, No. 23, Art. 142);

      3) The Law of the Republic of Kazakhstan,dated on December 10, 1999 "On compulsory treatment of citizens suffering from infectious tuberculosis" (the Bulletin of the Parliament of the Republic of Kazakhstan, 1999, No/ 24, Art. 1071, 2006, No. 15, Art. 92, 2007, No. 5-6, Art. 40);

      4) The Law of the Republic of Kazakhstan,dated on May 27, 2002 "On medical and social rehabilitation of drug addicts" (the Bulletin of the Parliament of the Republic of Kazakhstan, 2002, No. 10, Art. 104, 2004, No. 23, Art. 142);

      5) The Law of the Republic of Kazakhstan, dated on July 10, 2002 "On prevention and limitation of tobacco smoking" (the Bulletin of the Parliament of the Republic of Kazakhstan, 2002, No 15, Art. 149, 2006, No 23, Art. 141, 2007, No 12, Art. 88);

      6) The Law of the Republic of Kazakhstan dated on December 4, 2002 "On healthcare-epidemiological welfare of the population" (the Bulletin of the Parliament of the Republic of Kazakhstan, 2002, No 21, Art. 176, 2004, No 23, Art. 142, 2005, No 7-8, Art. 23, 2006, No 3, Art. 22; No 15, Art. 92, 2007, No 19, Art. 147; No 20, Art. 152, 2008, No 21, Art. 97);

      7) The Law of the Republic of Kazakhstan, dated on June 4, 2003 "On the health care system" (the Bulletin of the Parliament of the Republic of Kazakhstan, 2003, No 11, Art. 70, 2004, No 23, Art. 142, 2006, No 3, Art. 22; No 15, Art. 92; No 24, Art. 148; 2007, No 2, Art. 18; No 9, Art.. 67; No10, Art. 69; No 19, Art. 147; No20, Art. 152, 2008, No 23, Art. 124);

      8) The Law of the Republic of Kazakhstan, dated on January 13, 2004 "On Medicines" (the Bulletin of the Parliament of the Republic of Kazakhstan, 2004, № 2, Art. 8; No 23, Art.142, 2006, No 3, Art. 22; No 15, Art. 92; No 24, Art. 148, 2007, No 2, Art. 18; No 19, Art. 147; No 20, Art. 152, 2008, No 21, Art. 97);

      9) The Law of the Republic of Kazakhstan, dated on 16 June 2004 "On reproductive rights and guarantees of their implementation" (the Bulletin of the Parliament of the Republic of Kazakhstan, 2004, No 13, Art. 73, 2006, No 15, Art. 92, 2007, No 20, Art. 152);

      10) The Law of the Republic of Kazakhstan dated on June 28, 2005 "On donation of blood and its components" (the Bulletin of the Parliament of the Republic of Kazakhstan, 2005, No 12, Art. 45);

      11) The Law of the Republic of Kazakhstan, dated on July 7, 2006 "On protection of public health" (the Bulletin of the Parliament of the Republic of Kazakhstan, 2006, No 14, Art. 91, 2007, No 2, Art. 14).

*The President*

*of the Republic of Kazakhstan              Nursultan Nazarbayev*

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