



On public health and health care system

Unofficial translation

The Code of the Republic of Kazakhstan dated on September 18, 2009 No 193-IV. Abolished by the Code of the Republic of Kazakhstan dated July 7, 2020 No. 360-VI.

U n o f f i c i a l t r a n s l a t i o n

Footnote. Abolished by the Code of the Republic of Kazakhstan dated 07.07.2020 No. 360-VI (shall be enforced upon expiry of ten calendar days after the day of its first official publication) .

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) an authorized generic - a medicinal product identical to the original product, manufactured by the same manufacturer, but differing in trade name and price;

1-1) human environment (hereinafter - environment) - a combination of natural, anthropogenic and social factors, the environment (natural and artificial), that determine 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 preventing and eliminating of medical and sanitary consequences of social, natural and man-made emergency situations (hereinafter - emergency situations), including prevention and medical treatment of population, sanitary and anti-epidemic and sanitary-preventive measures, protection and rehabilitation of health of participants in the emergency situations liquidation, as well as medical assistance to the employees of rescue services;

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;

5-1) social health insurance fund - a non-profit organization that accumulates deductions and contributions, and also purchases and pays for the services of healthcare subjects, providing medical assistance in the amounts and on terms stipulated in the contract for the purchase of medical services and other functions, determined by the laws of the Republic Kazakhstan;

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;

13-1) a list of medicines and medical devices for free and (or) preferential outpatient provision of certain categories of citizens with certain diseases (conditions) - a list of medicines, medical devices and specialized medical products, procured at the expense of budget funds and assets of the social health insurance fund in the framework of the guaranteed volume of free medical care and in the system of compulsory social medical insurance for provision of outpatient aid, including names and characteristics of medicines, medical devices and specialized medicinal products for certain categories of people with certain medical conditions (conditions);

13-2) biosimilar medicines (bio-analogue, biosimilar drug, biosimilar) - a biological medicinal product that contains a version of the active ingredient of a registered biological original medicinal product or a reference medicinal product and for which a similarity (

similarity) is demonstrated based on comparative studies in quality indicators, biological activity, safety and efficacy;

13-3) biobank – a specialized storage of biological materials for scientific and medical purposes;

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 additives - natural and (or) biologically active substances identical to natural, as well as probiotic microorganisms, intended for use simultaneously with food or introduction into the composition of food products;

15-1) biological medicines - a medicinal product, the active substance of which is produced or isolated from a biological source and for the description of the properties and quality control of which a combination of biological and physico-chemical methods of analysis is needed with an assessment of the production process and methods of its control;

15-2) biotechnological medicine - a drug, produced using biotechnological processes and applying the methods using recombinant deoxyribonucleic acid technology, the controlled expression of genes, encoding production of biologically active proteins, hybridoma technologies, monoclonal antibodies or other biotechnological processes;

15-3) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

15-4) the marginal price for the trade name of the medicinal product for retail sale - the price for the trade name of the medicine, above which its retail sale cannot be carried out;

15-5) certificate of assignment of qualification category - a document of the established form, confirming the assignment of the relevant qualification category;

15-6) original medicinal product - a medicinal product with a new active substance, which was the first to be registered and placed on the global pharmaceutical market on the basis of a dossier containing the results of full preclinical (non-clinical) and clinical studies confirming its safety, quality, and effectiveness;

Note of RCLI!

Paragraph 1 shall be supplemented with sub-paragraph 15-7) in accordance with the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced from 01.01.2020).

16) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

16-1) a single distributor - a legal entity, carrying out, within the guaranteed volume of free medical care and in the system of compulsory social health insurance, activities in accordance with Article 77 of this Code;

16-2) hematopoietic stem cells - a part of the tissue of internal environment of the body, cells of the human bone marrow, possessing polypotency in the process of life, located in the bone marrow, peripheral blood (after stimulation) and cord blood;

16-3) homeopathic medicine - a medicinal product, produced according to homeopathic technology, using homeopathic raw materials in accordance with the requirements of the Pharmacopoeia of the Republic of Kazakhstan and (or) the Eurasian Economic Union or in their absence in accordance with the requirements of homeopathic pharmacopoeias;

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) medicine - an agent that is or contains a substance or combination of substances that comes into contact with the human body, intended for the treatment, prevention of human diseases or restoration, correction or change of its physiological functions by means of pharmacological, immunological or metabolic effects, or for diagnosis of human diseases and conditions;

18-1) a long-term contract for supply of medicines and medical devices - a civil law contract, concluded by a single distributor for a period of up to ten years with the manufacturers of medicines, medical products of the Republic of Kazakhstan or a contract manufacturing customer of medicines and medical products, located in the Republic of Kazakhstan, for the supply of medicines and medical devices, produced in accordance with the requirements of good manufacturing practice (GMP) for medicines and requirements of the international standard quality management system (ISO 13485) for medical devices, except for medical products of safety class of potential risk of application of 1 and 2a (except sterile); or with a subject in the field of circulation of medicines and medical devices that intends to create and (or) modernize the production of medicines and medical devices or contract manufacturing of medicines and medical devices with a drug manufacturer, located in the Republic of Kazakhstan in accordance with the requirements of good manufacturing practice (GMP) for medicines, and for medical devices in accordance with the requirements of the international standard quality management system (ISO 13485), except for medical products of safety class of potential risk of application of 1 and 2a (except sterile), in the manner, prescribed by the legislation of the Republic of Kazakhstan;

18-2) a long-term contract for storage and transportation of medicines and medical devices - a civil law contract for provision of services, concluded by a single distributor with a subject in the field of circulation of medicines and medical products - a resident of the Republic of Kazakhstan that meets the requirements of the good distribution practice (GDP);

18-3) the marginal price of the medicine - the price above which the sale of the medicinal product cannot be carried out;

18-4) a producer of medicines - an organization, engaged in the production of medicines and having a license to produce medicines;

18-5) a register of authorized persons of manufacturers of medicines - an information resource of the authorized body in the field of health care, containing information about the authorized persons of manufacturers of medicines;

18-6) rational use of medicines - drug treatment, corresponding to clinical indications, in the doses that meet the individual needs of the patient, for a sufficient period of time and at the lowest cost;

18-7) a web portal for procurement of medicines and medical devices - an information system that provides a single point of access to electronic services for procurement of medicines and medical devices within the guaranteed volume of free medical care and in the system of compulsory social health insurance;

18-8) a single operator in the field of procurement of medicines and medical devices (hereinafter - the single operator) - a legal entity determined by the authorized body in the field of health care in coordination with the authorized body in the field of public procurement;

19) is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);

20) a retail sale of medicines and medical devices - pharmaceutical activities, related to the purchase (other than import), storage, distribution, sale (except export) to the final consumer, destruction of medicines and medical products, carried out in accordance with the rules, approved by the authorized body in the field of health care;

20-1) contract manufacturing of medicines and medical devices (hereinafter referred to as contract manufacturing) - the production of medicines and medical devices on a contract basis at the production facilities of the manufacturers of medicines and medical devices, located in the Republic of Kazakhstan, which ensure full compliance with the requirements of the good production practices (GMP) for medicines;

21) wholesale sales of medicines and medical devices (distribution) - pharmaceutical activities related to the procurement (purchase), storage, import (import), export (export), sale (except for the sale to the public) without limiting the volume, transportation and destruction of medicines and medical devices, carried out in accordance with the rules, approved by the authorized body in the field of health care;

21-1) appropriate pharmaceutical practices in the sphere of medicinal products circulation (hereinafter - appropriate pharmaceutical practices) - health standards, covering all phases of the life cycle of medicines: Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), good distribution practice (GDP), good pharmacy practice (GPP), good pharmacovigilance practice (GVP) and other appropriate pharmaceutical practices;

21-2) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

21-3) regulatory document on the quality of medicines - a document, establishing requirements for quality control of a medicinal product during the post-registration period on

the basis of an examination of the medicinal product during its registration and containing a specification, description of analytical methods and tests of the medicinal product or a reference to such tests, and also relevant acceptability criteria for quality indicators;

22) circulation of medicinal products - an activity that includes the development, pre-clinical (non-clinical) research, testing, clinical research, examination, registration, pharmacovigilance, quality control, production, manufacturing, storage, transportation, import and export, supply, sale, transfer, use, destruction of medicinal products;

23) objects in the field of circulation of medicines and medical devices - a pharmacy, a pharmacy in health care organizations that provide primary medical and sanitary and (or) consultative and diagnostic assistance, a mobile pharmacy for remote rural areas, organized from a pharmacy, a pharmacy (distribution) warehouse, a warehouse for temporary storage of medicines, medical devices, optics store, medical devices store, a warehouse of medical devices, organizations for production of medicines and medical products;

24) subjects in the field of circulation of medicines and medical devices - individual or legal entities, engaged in pharmaceutical activities;

24-1) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

24-2) safety of medicines - the absence of unacceptable risk in the use of a medicine, associated with the possibility of causing harm to life, human health and the environment;

25) the State register of medicines and medical devices - an information resource, containing information on medicinal products and medical devices, registered and authorized for medical use in the Republic of Kazakhstan;

25-1) the efficacy of the medicine - a set of characteristics of the drug, ensuring the achievement of a preventive, diagnostic or therapeutic effect or restoration, correction or modification of the physiological function;

25-2) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

26) is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);

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 medicines - a set of properties and characteristics of a pharmaceutical substance (active pharmaceutical substance) and a medicinal product, ensuring their compliance with the intended purpose;

29-1) bulk product of medicines or medical device - a dosed finished medicinal product or a finished medical device that has passed all stages of the technological process, except for the final packaging;

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

30-1) dosage form - the state of the medicinal product, corresponding to the methods of its introduction, use and ensuring the achievement of the desired therapeutic effect;

30-2) medicinal plant raw materials - fresh or dried plants, algae, fungi or lichens, or parts thereof, whole or powdered, used for the production of medicines;

31) medicines - a medicinal product in the form of a dosage form, used for the diagnosis, treatment and prevention;

32) manufacture of medicines - pharmaceutical activities, related to the manufacture of drugs in pharmacies, with the acquisition of pharmaceutical substances (active pharmaceutical substances) for pharmaceutical use, storage, quality control, design and sale of manufactured medicines;

32-1) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

32-2) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

33) is excluded by the Law of the Republic of Kazakhstan dated 30.06.2017 No. 80-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

33-1) medicinal raw material - substances of vegetative, mineral, animal origin or products of chemical industry, used for production and manufacture of medicines;

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;

34-1) disinsection - a complex of preventive and exterminating measures for destruction of insects and arthropods in order to protect humans, animals, premises and territory from them;

34-2) disinfection - a set of special measures, aimed at destruction of pathogens of infectious and parasitic diseases in the external environment;

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;

36-1) health care system - an aggregate of state bodies and health care subjects whose activities are aimed at ensuring the rights of citizens to health protection;

36-2) health care manager - a specialist for management of a state legal entity in the field of health care or certain areas of activity of a state legal entity in the field of health care;

36-3) qualification category in the field of health care (hereinafter - the qualification category) - the level of qualification of a specialist, characterized by the volume of professional knowledge and skills necessary to perform work in the relevant medical and pharmaceutical specialty;

37) assessment of scientific and pedagogical staff of scientific organizations and educational organizations in the field of health care - the procedure for determining the level of pedagogical and professional competence of scientific and pedagogical personnel of scientific organizations and educational organizations in the field of health care;

37-1) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

37-2) professional standard in the field of healthcare - the standard, defining requirements to a level of qualification, content, quality and working conditions of specialists in the field of healthcare;

37-3) functional maintenance of the concession object in the healthcare sector - the use of the concession object in accordance with the intended purpose of the concession object, including for the production of goods and (or) the performance of work, and (or) the provision of services, in the manner and on the terms, determined by the concession agreement;

37-4) excluded by Law of the Republic of Kazakhstan No. 272-VI dated November 25, 2019 (shall be enforced upon expiry of ten calendar days after the day of its first official publication);

37-5) certification of healthcare professionals - a mandatory procedure for determining the compliance of medical workers with a clinical specialty and admitting them to clinical practice (working with patients), healthcare managers with the issuance of an appropriate specialist certificate;

38) expertise in the field of healthcare - a set of organizational, analytical and practical activities aimed at establishing the level and quality of measures, methods, technologies, educational programs, services in various fields of healthcare activities in accordance with the legislation of the Republic of Kazakhstan;

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) the authorized body in the field of health care (hereinafter referred to as the authorized body) - a central executive body responsible for management and inter-sectoral coordination in the field of health care, medical and pharmaceutical science, medical and pharmaceutical

education, sanitary and epidemiological welfare of the population, circulation of medicines and medical products, 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;

42-1) health care technology assessment - a comprehensive assessment of the comparative proven clinical and clinical-economic (pharmaco-economic) effectiveness and safety of health care technology, as well as the economic, social and ethical consequences of their use;

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

43-1) drug formulary of the organization of healthcare - the list of medicines for rendering medical aid within the limits of the guaranteed volume of free medical aid and in the system of obligatory social medical insurance, formed on the basis of the Kazakhstani national drug formulary and approved by the head of healthcare organization in the manner determined by the authorized body;

43-2) deratization - a complex of preventive and extermination measures aimed at destruction or reduction of the number of rodents;

43-3) detoxification - a complex of medical measures aimed at removing toxic substances of endogenous or exogenous origin from the human body;

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

45) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

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) donor - a person, a dead body, an animal from which donor blood, its components, other donor material (including sperm, eggs, germ cells, tissues of the reproductive organs, embryos) are taken, as well as the tissue (parts of tissue) and (or) organs (parts of organs), hematopoietic stem cells for transplantation to a recipient;

47-1) donor function - a voluntary act of a donor, including a medical examination and the procedure for giving blood and its components for medical purposes;

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;

49-1) undesirable reaction - an unintended, adverse reaction of the body, associated with the use of the medicines (test drug) and suggesting a possible relationship with the use of this (test) medicines;

50) falsified medicines and medical device – a medicinal product, medical device, illegally and deliberately supplied with inaccurate information and a fake label about their composition or configuration and (or) manufacturers of medicines and medical devices;

51) personal medical card - a personal document, where the results of mandatory medical examinations with a note of admission to work are recorded;

51-1) sanitary and epidemiological expertise of projects - a part of the project expertise, carried out as part of a comprehensive non-departmental project expertise (feasibility studies and design estimates), intended for the construction of new or reconstruction (expansion, retrofitting, modernization) and overhaul of existing facilities, integrated urban development expertise of urban development projects;

51-2) high-tech medical services - services provided by specialized experts in diseases requiring the use of innovative, resource-intensive and (or) unique methods of diagnosis and treatment;

51-3) planned medical care - medical care for preventive measures, diseases and conditions that do not require emergency and urgent medical care;

52) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

52-1) immunological medicines (immuno-biological drug) - a medicinal product, intended to form active or passive immunity or to diagnose the presence of immunity, or to diagnose (develop) a specific acquired change of the immunological response to allergic substances;

52-2) immunological typing system (hereinafter - the system-HLA) - an antigen system, located on human leukocytes and determining the tissue compatibility of the donor and recipient at transplantation of tissues (tissue parts) and (or) organs (parts of organs);

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;

54-1) integrated academic medical center – an association of a medical organization of higher and (or) postgraduate education with scientific and health care organizations to share resources for improving the quality of medical services by integrating education, research and clinical practice;

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;

57-1) emergency medical care - medical care for sudden acute illnesses, trauma, severe deterioration of health status, exacerbation of chronic diseases, without obvious signs of a threat to the life of the patient;

57-2) biological material of preclinical (non-clinical) and clinical researches - samples of biological fluids, tissues, secrets and products of vital activity of humans and animals, biopsy material, histological sections, smears, scrapings, flushes obtained during preclinical (non-clinical) and clinical studies and intended for laboratory research;

58) pre-clinical (non-clinical) research - chemical, physical, biological, microbiological, pharmacological, toxicological and other experimental research or a series of studies of a test (medicines) substance by applying scientific assessment methods in order to study a specific action and (or) to obtain the proofs of 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;

59-1) clinical protocol - a document that establishes general requirements for provision of medical care to a patient in a particular disease or clinical situation;

59-2) clinical pharmacologist - a specialist with higher medical education in "medical business", "pediatrics", "general medicine", who went through residency or retrained in clinical pharmacology and have a certificate of specialist of clinical pharmacologist;

59-3) consultation - a study of a person for the purpose of establishing a diagnosis, determining treatment tactics and prognosis of a disease with the participation of at least three doctors;

59-4) contraception - methods and means of preventing unwanted pregnancy;

59-5) operation of a healthcare facility created as a result of the implementation of a concession project (concession facility) - the use of a concession facility in the healthcare sector, which may provide for technical and functional services, in the manner and under the conditions determined by the concession agreement;

59-6) maintenance of the concession object - the use of the concession object in the healthcare sector with the implementation of a set of technological and organizational measures aimed at maintaining the concession object in the healthcare sector in a good, safe condition suitable for its functional maintenance, as well as the implementation of its current and (or) overhaul, management, performance of service and (or) auxiliary activities in the manner and on the terms determined by the concession agreement;

60) the maximum price for the trade name of a medicinal product for wholesale - the price for the trade name of a medicinal product, above which its wholesale cannot be carried out;

61) daily medical conference - a scheduled meeting of a medical organization with the aim of summarizing the results of the past day, discussing and analyzing clinical cases, as well as informing the team on new achievements in medical science and clinical practice;

61-1) Kazakhstan national drug formulary - a list of medicines with proven clinical safety and efficacy, as well as orphan (rare) drugs, which is a mandatory basis for the development of medicinal formulars of medical organizations and formation of lists of procurement of medicines within the guaranteed volume of free medical care and in the system of compulsory social health insurance;

61-2) nomenclature of medical products of the Republic of Kazakhstan - a systematic nomenclature classifier of types of medical devices, harmonized with the Global Medical Device Nomenclature (GMDN) and used in the Republic of Kazakhstan;

61-3) register of pharmaceutical inspectors of the Republic of Kazakhstan - an information resource of the authorized body, containing information on the pharmaceutical inspectors of the Republic of Kazakhstan;

62) the State pharmacopoeia of the Republic of Kazakhstan - a set of minimum requirements for the safety and quality of medicines and medical devices;

62-1) reproduced medicine (generic) - a medical product that has the same quantitative and qualitative composition of the active ingredients and the same dosage form as the original drug, and whose bioequivalence to the original drug is confirmed by the relevant bioavailability studies. Different salts, ethers, isomers, mixtures of isomers, complexes or derivatives of the active substance are recognized as the same active substance, if their safety and effectiveness do not differ significantly. Various oral dosage forms for immediate release of substances are recognized in the frames of bioavailability studies as the same dosage form;

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;

63-1) research in the field of public health - a study, conducted on the basis of collecting and summarizing clinical and epidemiological data and other medical information to identify the main factors, affecting health and determining the development of the health care system, developing methods of directional influence and managing these factors;

63-2) adverse event (incident) - any malfunction and (or) deterioration of the characteristics or malfunction of the medical device, or insufficiency or incorrectness of the accompanying information (documentation) on the medical device, side effects or undesirable reaction that are not indicated in the instructions for use or operation manual, which directly or indirectly resulted or could cause death or serious deterioration of the health of users or third parties;

63-3) excipient - a substance, except for pharmaceutical substances (active pharmaceutical substances), which is part of a medicinal product to give it the necessary properties;

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

64-1) assessment of professional preparedness and confirmation of compliance with the qualifications of specialists - the procedure for assessing knowledge and skills, conducted in order to confirm the compliance of the specialist's qualifications with the requirements of the professional standard in the field of healthcare;

65) a certificate of a specialist - a document of the established form, confirming the qualification of an individual for compliance with: clinical specialty and for his admission to clinical practice (work with patients); health care manager;

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;

68-1) medical and biological experiment - a study, based on simulation (modeling) of a structural-functional complex of a studied condition or disease in a simplified form on laboratory animals to find out the causes, conditions and mechanisms for the occurrence or development of a disease, development of treatment and prevention methods;

68-2) medical education - a system of training, retraining and advanced training of medical workers, as well as a set of knowledge and skills necessary for a medical worker, obtained during training in training, retraining and advanced training programs in medical specialties, confirmed by an official certificate of completion of training;

68-3) strategic partnership in the field of medical education and science - a form of medium-term or long-term cooperation between scientific organizations and educational organizations in the field of health care, and foreign organizations of higher and (or) postgraduate education, and medical organizations in the field of medical education and science for introduction and adaptation of international standards of education, science and clinical practice on the basis of a contract;

68-4) circulation of medical devices - design, development, creation of prototypes, conduct of technical tests, studies (testing) of assessment of the biological effect of medical devices, clinical studies, examination of safety, quality and efficiency of medical devices, registration, production (manufacturing), storage, transportation, sale, installation, commissioning, application (operation), maintenance, repair and disposal of medical products ;

68-5) studies (testing) of assessment of the biological effect of medical devices – the studies (testing), conducted to determine the compliance of medical devices with the general safety requirements and effectiveness of medical devices, the requirements for their labeling and their operational documentation;

68-6) the global medical device nomenclature (GMDN) - a systematized nomenclature classifier of types of medical devices, used to identify medical devices;

68-7) monitoring of the safety, quality and effectiveness of medical devices – a collection, registration, analyses of information about adverse events (incidents);

68-8) type of medical devices - a group of medical devices having a similar purpose, similar application technologies, design features and a common digital designation in the nomenclature of medical products of the Republic of Kazakhstan;

68-9) medical device manufacturer - a subject in the field of circulation of medicines and medical devices, responsible for the development and manufacture of a medical device, making it available for use on its own behalf, regardless of whether it has been developed and (or) manufactured by this person or on behalf of another person (s) responsible for its safety, quality and effectiveness;

68-10) safety of a medical product - the absence of unacceptable risk when using a medical product associated with harm to human life, health, and the environment;

68-11) quality of a medical product - the degree of compliance of the set of properties and characteristics of a medical product with the objectives of its intended use;

68-12) trade name of a medical device - the name under which the medical device is registered;

68-13) effectiveness of a medical product - a set of properties and characteristics of a medical product, ensuring the achievement of the goals, established by the manufacturer of the medical product and confirmed by the practice of its use;

68-14) a medical research - a study, aimed to obtain new knowledge through scientific methods about human health, diseases, their diagnosis, treatment or prevention;

69) is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);

70) medical assistance - a complex of medical services, including medicinal assistance, aimed at preserving and recovering of public health, as well as alleviating severe manifestations of incurable diseases;

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 - actions of subjects of healthcare, having preventive, diagnostic, medical, rehabilitation or palliative orientation in relation to a special person;

75) medical devices - any tools, apparatuses, devices, equipment, materials and other products that are used for medical purposes separately or in combination with each other, as well as with the accessories necessary for using these products for their intended purpose,

including special software, intended for prevention, diagnosis, treatment of diseases, medical rehabilitation and monitoring of the state of the human body, conduct of a medical research, restoration, substitution, alteration of the anatomical structure or physiological functions of the body, prevention or termination of pregnancy and the functional purpose of which is not realized by pharmacological, immunological, genetic or metabolic effects on the human body and can be supported by the use of drugs;

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) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

78-1) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

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

79-1) nursing care - a complex of medical services, rendered by paramedical workers to people with serious illnesses who need care, in the cases that do not require medical supervision;

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;

80-1) state registration certificate - a document, confirming the safety of products (goods), certifying the conformity of products (goods) to the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of the population and hygienic standards;

80-2) state pharmaceutical inspector - an official of the authorized body that carries out state control in the field of circulation of medicines and medical devices, aimed at preventing, identifying and preventing violations of the legislation of the Republic of Kazakhstan in the field of health care;

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 (rare) medicine - a drug intended for diagnosis, etiopathogenetic or pathogenetic treatment of orphan (rare) diseases, the frequency of which does not exceed the officially determined level in the Republic of Kazakhstan;

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;

84-1) focal disinfection - disinfection, conducted in the foci for the purpose of prevention and (or) elimination of infectious and parasitic diseases;

84-2) production control - a set of measures, including laboratory research and testing of products, works and services, performed by an individual entrepreneur or a legal entity, aimed at ensuring safety and (or) harmlessness to humans and their environment;

84-3) monitoring of product safety - a system of measures aimed at identifying, preventing and suppressing import, production, use and sale of products that do not meet the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of the population, hygienic standards and technical regulations;

84-4) an authorized person of a manufacturer - a person responsible for ensuring and controlling the quality of medicines, produced by the manufacturer in accordance with the legislation of the Republic of Kazakhstan in the field of health care, and included in the register of authorized persons of manufacturers of medicines;

84-5) a production site - a geographically isolated complex of a manufacturer of medicines, medical devices, designed to perform the entire process of manufacturing of medicinal products, medical devices, or its specific stages;

84-6) palliative care - a complex of medical services, aimed at improving the quality of life of patients with incurable diseases in the terminal (final) stage;

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;

90-1) psychological assistance - a set of activities aimed at:

assistance to a person in preventing, resolving psychological problems, overcoming difficult life and crisis situations and their consequences, contributing to the maintenance of mental and physical health, optimizing mental development, adapting and improving the quality of life, including by activating one's own capabilities;

informing people about the causes of psychological problems, ways to prevent and resolve them;

development of the personality, its self-improvement and self-realization;

90-2) psychological problem - the state of a person's mental discomfort, caused by dissatisfaction with him(her)self, his (her) activities, interpersonal relationships, family situation and (or) other personal problems;

90-3) radiopharmaceutical medicine - a drug that contains one or more radionuclides (radioactive isotopes) in ready-for-use condition as an active substance or as part of an active substance;

90-4) reference medicine - a drug that is used as a comparison drug and is the standard by which the properties of a medicine are determined (normalized);

91) the recipient - a patient who is transfused with donor blood or components and(or) preparations extracted from it, insertion of male or female donor material (sperm, egg, embryos) or transplantation of tissue (tissue part) and (or) organ) from the donor;

91-1) sanatorium-resort treatment - a type of recovering treatment and (or) medical rehabilitation, conducted in the conditions of temporary stay of persons in the sanatorium-resort organization;

92) sanitary and quarantine control - control over the sanitary and epidemiological condition of cargo and people's health state, when transporting people and cargos across the State border of the Republic of Kazakhstan, coinciding with the customs border of the Eurasian economic union, conducted in order to prevent the importation of infectious and parasitic diseases into the country, as well as substances and products that are 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;

93-1) sanitary and preventive measures - measures taken to prevent infectious, parasitic, occupational and other diseases among the population, as well as to prevent infectious and parasitic diseases among the population from entering the territory of the Republic of Kazakhstan;

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

94-1) sanitary and epidemiological audit - check of epidemically significant objects subject to state sanitary and epidemiological surveillance for identification and assessment of sanitary and epidemiological risks and development of recommendations on bringing these objects in compliance with the requirements of regulatory legal acts in the field of sanitary and epidemiological well-being of the population;

94-2) sanitary and epidemiological conclusion - a document, certifying compliance (non-compliance) with normative legal acts in the field of sanitary and epidemiological welfare of the population, hygienic standards and (or) technical regulations of the objects of state sanitary and epidemiological surveillance;

95) sanitary and anti-epidemic measures - measures taken to localize and eliminate the emergent foci of infectious, parasitic diseases, poisoning among the population;

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 hematopoiesis, located in the spongy substance of bones and bone-marrow cavities;

95-3) standard sample - an identified homogeneous substance or a mixture of substances, intended for use in chemical, physical and biological research, in which its (its) properties are compared with the properties of the studied medicinal product, and possessing a degree of purity sufficient for appropriate use;

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 - justification of the likelihood of penetration and spread of pathogens or vectors of infectious and parasitic diseases, as well as the negative impact of environmental factors on the health of the population and the associated medical, biological and economic consequences;

98) independent expertise - a procedure carried out by independent experts within the framework of external expertise in order to draw an opinion on the level of quality of medical services, provided by healthcare subjects, using indicators reflecting the indicator of effectiveness, completeness and compliance of provided medical services with standards;

98-1) an independent expert - an individual, having a higher medical education and meeting the requirements for individuals applying for carrying out an independent expertise, by a certain authorized body;

99) guaranteed volume of free medical care - the volume of medical assistance provided by budgetary funds according to the list determined by the Government of the Republic of Kazakhstan to the citizens of the Republic of Kazakhstan, repatriates, as well as foreigners and stateless persons permanently residing on the territory of the Republic of Kazakhstan;

99-1) is excluded by the Law of the Republic of Kazakhstan dated 30.06.2017 No. 80-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

99-2) marginal price for the trade name of a medicinal product or a medical device in the framework of the guaranteed volume of free medical care and in the system of compulsory

social health insurance - the price of the trade name of the medicinal product or medical device above which the purchase cannot be made within the guaranteed volume of free medical care and the system of compulsory social health insurance;

99-3) telemedicine - a complex of organizational, financial and technological measures ensuring the implementation of a distance medical consulting service, when a patient or a doctor directly examining or treating a patient, receives a distance consultation from another doctor using information and communication technologies that do not contradict national standards ;

99-4) marginal price for the international non-patented name of a medicinal product or technical specification of a medical product within the guaranteed volume of free medical care and in the system of compulsory social medical insurance - the price for the international non-patented name of the medicinal product or technical specification of a medical product, above which it cannot be procured in the framework of the guaranteed volume of free medical care and in the system of compulsory social health insurance;

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

101) tobacco products - products that are wholly or partly made of tobacco leaf as a raw material, prepared in such a way as to be used for smoking, sucking, chewing or sniffing;

101-1) consumption of tobacco products - the process of consumption of a tobacco product that causes the dependence of the human body on nicotine, negatively affecting his/her health, as well as on the health of persons not consuming tobacco products and polluting the environment;

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;

104-1) sponsorship of tobacco - any type of contribution to any occasion, event or individual with the purpose, effect or likely effect of encouraging the sale of a tobacco product or the use of tobacco, directly or indirectly, with the exception of payments and contributions provided by the legislation of the Republic of Kazakhstan;

104-2) pharmaceutical inspector on good pharmaceutical practices - a person, authorized to perform the functions of conducting pharmaceutical inspection on good pharmaceutical practices and included in the register of pharmaceutical inspectors of the Republic of Kazakhstan in accordance with the procedure, determined by the authorized body;

105) is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);

105-1) pharmaceutical inspectorate on good pharmaceutical practices (hereinafter – the pharmaceutical inspectorate) - evaluation of an object in the field of circulation of medicines in order to determine its compliance with the requirements of the good pharmaceutical practices of the Republic of Kazakhstan and (or) the Eurasian Economic Union;

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) tissue - a collection of cells and intercellular substance, having the same structure, functions and origin;

107-2) a registry of donors of tissue (part of tissue) and (or) organs (part of organs) - a database of persons who agree to donate the tissue (parts of tissue) and (or) organs (parts of organs), hematopoietic stem cells, typed by HLA system;

107-3) the register of tissue recipients (tissue parts) and (or) organs (parts of organs) - the database of persons who need tissue transplantation (tissue parts) and (or) organs (parts of organs), typified by the HLA- system;

107-4) temporary adaptation - the process of removing a person from the state of alcohol intoxication and his/her adapting to environmental conditions;

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;

108-1) university clinic - a highly specialized treatment-and-prophylactic structural subdivision of a medical organization of higher and (or) post-graduate education or a highly specialized treatment-and-prophylactic organization that is in trust management or a subsidiary of a medical organization of higher and (or) postgraduate education, which conducts training, retraining and advanced training of medical personnel, based on modern achievements of science and practice and, providing all types of medical care;

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

109-1) assisted reproductive methods and technologies - methods of treatment of infertility (artificial insemination, artificial insemination and embryo implantation), in application of which some or all stages of conception and early development of embryos shall be carried out outside the maternal organism (including using donor and (or) cryopreserved germ cells, tissues of reproductive organs and embryos, as well as surrogate motherhood);

109-2) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

110) pharmacological product - a substance or a mixture of substances with established pharmacological activity and toxicity, which are the subject of preclinical (non-clinical) and clinical studies; and a potential drug;

110-1) pharmacovigilance - an activity, aimed at identifying, analyzing, evaluating and preventing undesirable consequences of the use of medicines;

110-2) pharmacovigilance system - a system, organized by the holders of the registration certificates of medicines and an authorized body to perform the tasks and duties on pharmacovigilance, designed to monitor the safety of medicines, timely identify all changes in the assessment of the benefit-risk ratio of medicines, develop and take measures to ensure the use of medicines in excess of the benefit over the risk;

110-3) pharmaceutical substance (active pharmaceutical substance) - a medicinal product, intended for production and manufacture of medicines;

110-4) formulary system - a system of periodic evaluation and selection of medicinal products for medicinal formulations, maintaining medicinal formularies and providing information in the form of appropriate guidance and a list, aimed at the rational use of medicinal products;

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

111-1) pharmaceutical education - the system of training, retraining and qualification development of pharmaceutical workers;

111-2) pharmaceutical service - the activities of subjects in the field of circulation of medicines and medical devices, related to outpatient drug provision of the population, including the procurement, transportation, storage, accounting and sale of medicines and medical devices, within the guaranteed volume of free medical care and the system of compulsory social health insurance;

112) pharmaceutical activity - the activity, carried out in the field of health care for production, manufacture, wholesale and retail sale of medicines and medical devices, related to the procurement (purchase), storage, import, export, transportation, quality control, clearance, distribution, use and destruction of medicines and medical devices, as well as ensuring their safety, quality and efficacy;

112-2) functional operator - a state legal entity or a legal entity with one hundred percent participation of the state in the authorized capital or its subsidiary, more than fifty percent of the voting shares (participatory interest) in the authorized capital of which it owns, the statutory activity of which is the provision of medical assistance that is not a party to the concession agreement, determined by the Government of the Republic of Kazakhstan for the implementation of activities related to the functional maintenance of the concession object;

112-3) decreed population group - persons working in the field of public services and posing the greatest danger to infecting people around with infectious and parasitic diseases;;

113) products posing a danger to public health - types of products established by the state body in the field of sanitary and epidemiological welfare of the population, which can have a harmful effect on human health when applied or used;

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 the sphere of sanitary and epidemiological welfare of population - the activity of state bodies and organizations of sanitary and epidemiological service aimed at protecting the health of citizens, including state sanitary and epidemiological control and supervision, sanitary and quarantine control, radiation control, epidemiological control, sanitary - epidemiological regulation, state registration of food products and certain types of products and substances that have a harmful effect on the health of a person, sanitary and epidemiological monitoring, sanitary and epidemiological expertise, hygienic training, assessment of the degree of risks in the sanitary and epidemiological welfare of population;

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;

118-1) emergency medical assistance - medical assistance, requiring immediate medical intervention to prevent significant harm to health or eliminate the threat to life in case of sudden acute illnesses, injuries, severe deterioration in health, exacerbation of chronic diseases in accordance with the list determined by the authorized body;

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) epidemically significant objects - objects, which produced products and (or) activities, if the requirements of the legislation of the Republic of Kazakhstan in the sphere of sanitary and epidemiological welfare of the population are violated, may result in food poisoning and (or) infectious and parasitic diseases among the population and (or) inflict harm to the health of population from industrial and radioactive contaminations;

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;

123) medical devices for in vitro diagnostics - any instruments, apparatuses, devices, equipment, materials, reagents, calibrators, control materials and other products, used for medical purposes separately or in combination with each other, as well as with accessories

required for use of specified products for the intended purpose, including special software, and intended for use in in vitro studies of samples of human biological materials for obtaining information about a physiological or pathological condition, congenital disorders, predisposition to certain clinical condition or disease, tissue compatibility with potential recipients, predicting responses to therapeutic effects, selection of therapeutic agents and (or) control of treatment.

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); dated 21. 06. 2013 № 107-V (shall be enforced upon expiry of thirty calendar days after its first official publication); by the Constitutional Law of the Republic of Kazakhstan dated 03.07.2013 No. 121-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 29.12. 2014 No. 269-V (shall be enforced from 01.01.2015); dated 06.04.2015 № 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2017); dated 03.12.2015 No. 433-V (shall be enforced from 01.01.2016); dated 29.03.2016 No. 479-V (shall be enforced from 01.01.2017); dated 27.02.2017 No. 49-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 30.06.2017 No. 80-VI (the procedure for enactment see Article 2); dated 26.12. 2017 No. 124-VI (shall be enforced from 01.01.2018); dated 28.12.2018 No. 208 -VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication); No. 272-VI dated November 25, 2019 (shall be enforced upon expiry of ten calendar days after the day of its first official publication); No. 287-VI dated 26.12.2019 (shall be enforced since 01.01.2020).

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. Legal relations, regulated by the legislation of the Republic of Kazakhstan in the field of health care shall not apply to the legislation of the Republic of Kazakhstan on public procurement in the part of:

1) purchase of services from healthcare subjects within the guaranteed volume of free medical care and in the system of compulsory social health insurance;

2) procurement of medicines and medical devices in the framework of the guaranteed volume of free medical care and in the system of compulsory social medical insurance;

3) procurement of services for the storage and transportation of medicines and medical devices in the framework of the guaranteed volume of free medical care and in the system of compulsory social health insurance;

4) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

4-1) effective until 01.01.2018 in accordance with the Law of the Republic of Kazakhstan dated 16.11.2015 No. 406-V;

5) procurement of goods and services for examination during the state registration, re-registration and introduction of changes to the registration dossier of medicines, medical devices and evaluation of their safety and quality;

6) purchase of pharmaceutical services;

7) procurement of services for the registration and sale of medicines and medical devices within the framework of the guaranteed volume of free medical care and in the system of compulsory social medical insurance.

3. Requirements for medical examination, medical examination in the field of civil aviation for aviation personnel, as well as categories of persons subject to mandatory medical check-up and medical examination, shall be established by the legislation of the Republic of Kazakhstan on the use of the airspace of the Republic of Kazakhstan and aviation activities.

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); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 № 406-V (the procedure for enactment see Article 3); dated 10.05.2017 No. 64-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 30.06.2017 No. 80-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (the order of enforcement, see Art. 2).

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) state support of national medical and pharmaceutical science, introduction of advanced achievements of science and technology in the field of prevention, diagnosis, treatment and medical rehabilitation, innovative development of new medicines and technologies, as well as world experience in the field of 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.
- 18) ensuring the availability of safe, high-quality and effective medicines, medical devices and their rational use.

Footnote. Article 4 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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;

2-1) licensing of importation into the territory of the Republic of Kazakhstan from countries outside the Eurasian Economic Union, and the exportation from the territory of the Republic of Kazakhstan to these countries of organs (parts of organs) and (or) human tissues, blood and its components;

3) accreditation in healthcare area;

4) certification in healthcare area;

4-1) certification of specialists in the field of healthcare;

5) state registration, re-registration and changes in the registration dossier of medicines, medical devices, certain types of products and substances that have a harmful effect on human health;

6) confirmation of compliance of goods (works, services) in the field of health care with the requirements, established by the technical regulations, standardization documents and contract terms, except for medicines, medical devices and medical equipment;

7) state regulation of prices for medicines, medical devices and medical services in the framework of the guaranteed volume of free medical care and in the system of compulsory social medical insurance;

8) state regulation of prices for medicines sold by subjects in the field of circulation of medicines and medical devices;

9) pharmaceutical inspection.

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); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 26. 12. 2017 No. 124-VI (shall be enforced from 01.01.2018); dated 05.10.2018 No. 184-VI (shall be enforced upon expiry of six months after its first official publication); dated 28.12.2018 No. 211-VI (the order of enforcement, see Art. 2).

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) publish, within its competence, normative legal acts in the field of public healthcare;

- 3) is excluded by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 4) is excluded by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 5) is excluded by the Law of the Republic of Kazakhstan dated 29.09.2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 6) manage the central and local authorities on healthcare issues;
- 7) is excluded by the Law of the Republic of Kazakhstan dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2016);
- 8) is excluded by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 9) determine the procedure, types and volume of medical assistance to the population in emergency situations, introduction of the state of emergency;
- 10) is excluded by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 11) is excluded by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 12) determine the procedure for organizing and conducting the procurement of medicines and medical devices, pharmaceutical services;
- 12-1) is excluded by the Law of the Republic of Kazakhstan dated 29.09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 12-2) determine the procedure for procurement of services for the storage and transportation of medicines and medical devices, services for the accounting and sale of medicines and medical devices by a single distributor within the guaranteed volume of free medical care and in the system of compulsory social medical insurance;
- 13) is excluded by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 14) is excluded by the Law of the Republic of Kazakhstan dated 29.09.2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 15) is excluded by the Law of the Republic of Kazakhstan dated 29.09.2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 16) is excluded by the Law of the Republic of Kazakhstan dated 29.09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 17) is excluded by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 18) determine the list of diseases against which prophylactic vaccinations are carried out, the procedure, the timing of their implementation and the population groups that are subject to the planned vaccinations;

19) is excluded by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);

20) is excluded by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);

21) is excluded by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);

22) is excluded by the Law of the Republic of Kazakhstan dated 29.09.2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);

23) determine the cases of import into the territory of the Republic of Kazakhstan of medicines and medical devices as humanitarian aid that have not passed the state registration in the Republic of Kazakhstan;

24) is excluded by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);

25) is excluded by the Law of the Republic of Kazakhstan dated 29.09.2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);

26) is excluded by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);

27) define a single distributor;

27-1) is excluded by the Law of the Republic of Kazakhstan dated 03.07.2013 No. 124-V (shall be enforced upon expiry of ten calendar days after its first official publication);

27-2) is excluded by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);

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); dated 03.07.2013 № 124-V (shall be enforced upon expiry of ten calendar days after its first official publication); by the Constitutional Law of the Republic of Kazakhstan dated 03.07.2013 No. 121-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 № 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 № 406-V (shall be enforced from 01.01.2016); dated 30.06.2017 № 80-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after 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) is excluded by the Law of the Republic of Kazakhstan dated 13.01.2014 No. 159-V (shall be enforced upon expiry of ten calendar days after its first official publication);
 - 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) development and approval of standards and regulations in the field of healthcare;
 - 6-1) development and approval of rules for the use of technical means of control, surveillance and fixation devices, photo and video equipment, used in medical organizations to ensure the protection of patients' rights;
 - 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) coordination of activities of health care subjects;
 - 8-1) coordination and monitoring of activities on corporate governance in state legal entities in the field of health care;
 - 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) development and approval of rules for encouragement of employees of healthcare subjects providing medical services within the guaranteed volume of free medical care and in the system of compulsory social health insurance;
 - 11-1) development and approval of the rules for conferring honorary titles in the field of 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) placement of the state educational order for training, retraining and qualification development of personnel in the field of 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) formation and approval of marginal prices and extra charges;
- 20-1) implementation of state regulation of prices for medicines;
- 20-2) implementation of state regulation of prices for medical products within the framework of the guaranteed volume of free medical care and in the system of compulsory social medical insurance;
- 20-3) approval of the list of medical products, procured by a single distributor in the framework of long-term contracts for the supply of medical devices at the marginal prices, established for medical products;
- 21) carry out outputs on equipping of public healthcare organizations;
- 22) is excluded by the Law of the Republic of Kazakhstan dated 30.06.2017 No. 80-VI (shall be enforced from 01.01.2018);
- 22-1) is excluded by the Law of the Republic of Kazakhstan dated 30.06.2017 No. 80-VI (shall be enforced from 01.01.2018);
- 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) the organization and conduct of state certification of educational organizations in the field of health care;
- 25) holding the attestation for professional competence of specialists in the field of healthcare, specified in paragraph 3 of Article 15 of this Code;
- 25-1) determining the procedure of attestation for professional competence of specialists in the field of healthcare;
- 25-2) monitoring the activities of accredited subjects of healthcare;
- 26) organize accreditation of healthcare subjects;
- 27) is excluded by the Law of the Republic of Kazakhstan dated 29.03.2016 No. 479-V (shall be enforced from 01.01.2017);
- 27-1) accreditation of organizations, carrying out an assessment of professional preparedness and confirmation of compliance with the qualifications of specialists in the field of healthcare;
- 28) is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 28-1) development and approval of standards for equipping simulation offices (centers) of educational organizations in health care;

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) development and approval of rules for assessing the safety and quality of medicines and medical devices, registered in the Republic of Kazakhstan;

29-2) development and approval of the rules for the formation of the register of health care subjects, engaged in the wholesale and retail sale of medical devices in a notification procedure;

29-3) is excluded by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication);

29-4) licensing of the importation into the territory of the Republic of Kazakhstan from countries outside the Eurasian Economic Union, and the exportation from the territory of the Republic of Kazakhstan to these countries of organs (parts of organs) and (or) human tissues, blood and its components;

29-5) determining the procedure for issuing conclusions (permits) for importation into the territory of the Republic of Kazakhstan and removal of hematopoietic stem cells from the territory of the Republic of Kazakhstan, bone marrow in case of their movement for the purpose of unrelated transplantation, as well as samples of cells, tissues, biological fluids and secrets, including the products of human vital activity, physiological and pathological discharge, smears, scrapings, washings intended for diagnostic scientific purposes or obtained in the process of conducting biomedical research;

29-6) the issuance of opinions (permits) for the importation into the territory of the Republic of Kazakhstan of medicines and medical devices, including unregistered ones, as humanitarian aid or assistance in emergency situations;

29-7) is excluded by the Law of the Republic of Kazakhstan dated 06. 04. 2015 № 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);

29-8) the licensing of the types of pharmaceutical activities provided for in subparagraphs 1), 2), 3), 4), 5) and 7) of paragraph 2 of Article 66 of this Code, as well as activities related to trafficking of narcotic drugs, psychotropic substances and precursors in the field of health care;

30) recognition of the requirements of the leading pharmacopoeias of the world, as well as international and interstate standards for medicinal products and medical devices in the Republic of Kazakhstan;

31) state registration, re-registration and introduction of changes to the registration dossier , withdrawal of the decision on state registration of medicinal products and medical devices, and maintenance of the State register of medicines and medical products;

32) approval of the importation (exportation) of medicinal products and medical devices, registered and unregistered in the Republic of Kazakhstan;

33) is excluded by the Law of the Republic of Kazakhstan dated 06 .04. 2015 № 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);

- 34) is excluded by the Law of the Republic of Kazakhstan dated 06. 04. 2015 № 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 35) is excluded by the Law of the Republic of Kazakhstan dated 13.01.2014 No. 159-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 36) is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 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) ensuring the organization of sociological research to determine the degree of satisfaction of citizens with the level and quality of medical care provided in accordance with the legislation of the Republic of Kazakhstan on state social order, grants, and awards for non-governmental organizations in the Republic of Kazakhstan;
- 41) consider applications of individuals and legal entities on healthcare issues;
- 42) organization of forming a healthy lifestyle and healthy nutrition;
- 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) is excluded by the Law of the Republic of Kazakhstan dated 06.04. 2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 45) is excluded by the Law of the Republic of Kazakhstan dated 06. 04. 2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 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) the implementation of state control over the activities of health care subjects;
- 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) implementation of state control in the sphere of provision of medical services;
- 50) implementation of state control in the fields of circulation of medicines and medical devices, the sanitary and epidemiological welfare of the population, as well as the circulation of narcotic drugs, psychotropic substances and precursors in the field of health care;
- 50-1) is excluded by the Law of the Republic of Kazakhstan dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication);
- 51) is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 52) is excluded by the Law of the Republic of Kazakhstan dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

- 53) is excluded by the Law of the Republic of Kazakhstan dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication);
- 54) consider cases on administrative offenses and imposes administrative penalties in accordance with the legislature of the Republic of Kazakhstan on administrative offences;
- 55) is excluded by the Law of the Republic of Kazakhstan dated 06. 04. 2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 56) organizing and conducting preventive vaccinations to the public;
- 57) is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 57-1) is excluded by the Law of the Republic of Kazakhstan dated April 6, 2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 58) is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 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) is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication);
- 61) is excluded by the Law of the Republic of Kazakhstan dated 29. 12. 2014 No. 269-V (shall be enforced from 01.01.2015);
- 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) development and approval of the State Pharmacopoeia of the Republic of Kazakhstan, its individual volumes or individual pharmacopoeial articles (monographs);
- 66) conduct international cooperation in the healthcare area, including medical and pharmaceutical science, medical and pharmaceutical education;
- 66-1) inter-sectoral coordination of activities for introduction and execution of international medical and sanitary rules;
- 66-2) development and approval of a provision on the status and powers of the national coordinator for the international medical and sanitary rules and the global public health program;
- 67) is excluded by the Law of the Republic of Kazakhstan dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication);
- 67-1) development and approval of rules for the ethical promotion of medicines and medical devices;

68) determining the list of medicines and medical devices, procured from a single distributor;

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);

69-1) approval of the Kazakhstani national drug formulary;

70) determining the order of formation of the Kazakhstan national medicinal formulary, the list of medicinal products and medical devices for free and (or) preferential outpatient provision of certain categories of citizens with certain diseases (conditions), as well as the development of medicinal formulars of health care organizations;

70-1) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

70-2) determining the procedure for assessing the rational use of medicines;

71) development and approval of rules for the formation of a pharmaceutical inspectorate, the maintenance of the register of pharmaceutical inspectors of the Republic of Kazakhstan;

71-1) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

72) is excluded by the Law of the Republic of Kazakhstan dated 29.12.2014 No. 269-V (shall be enforced from 01.01.2015);

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

74) approval of qualification requirements for medical and pharmaceutical activities;

75) is excluded by the Law of the Republic of Kazakhstan dated 16.11.2015 No. 406-V (shall be enforced from 01.07.2017);

76) determining the procedure for accreditation in the field of healthcare;

77) development and approval of the rules for the receipt of guaranteed volume of free medical care by the citizens of the Republic of Kazakhstan, repatriates, as well as foreigners and stateless persons permanently residing on the territory of the Republic of Kazakhstan,;

78) approval of the list of clinical databases;

79) approval of the standard contract form for providing a guaranteed volume of free medical care and paid services in healthcare organizations;

80) approval of the rules of sending citizens of the Republic of Kazakhstan for treatment abroad at the expense of budgetary funds;

81) excluded by Law of the Republic of Kazakhstan No. 80-VI dated 30.06.2017 (shall be enforced since 01.01.2020);

82) determining the order of collection, storage and use of blood and tissues of persons exposed to ionizing radiation;

83) approval of the procedure for providing medicines to citizens;

83-1) development and approval of the rules for the formation of lists of procurement of medicines and medical devices in the framework of the guaranteed volume of free medical care and in the system of compulsory social health insurance;

83-2) development and approval of the rules for the implementation of co-payment ;

84) development and approval of the rules for assessing the safety and quality of medicines and medical devices, registered in the Republic of Kazakhstan;

85) approval of the procedure and conditions for committing and transferring of anatomical gift to healthcare organizations;

86) approval of the state standard of the network of healthcare organizations;

86-1) development and approval of the rules for the formation, coordination and approval of a single long-term plan for development of health care infrastructure;

86-2) formation of a unified long-term plan for development of health care infrastructure;

86-3) coordination of regional long-term plans for development of health care infrastructure;

87) determining the procedure and conditions for the provision of paid services in healthcare organizations;

88) determining the procedure of payments to donors for the donation of blood and its components;

89) approval of the list of socially significant diseases and diseases that are dangerous for others;

89-1) development and approval of a list of diseases, associated with the impact of the ionizing radiation, and the rules for establishing a causal relationship;

90) approval of the procedure for the expertise of temporary incapacity for work, as well as issuing a leave and a certificate of temporary incapacity for work;

91) approving the procedure for providing medical assistance;

92) approval of the procedure for providing medical and social assistance to citizens suffering from socially significant diseases;

93) approval of the procedure for providing consultative and diagnostic assistance;

94) approving the procedure for providing inpatient assistance;

95) approval of the procedure for providing hospital-replacement assistance

96) approval of the procedure for providing emergency medical assistance;

97) approval of the procedure for providing medical assistance in the form of sanitary aviation;

98) approval of the order of rehabilitation treatment and medical rehabilitation, including children's medical rehabilitation;

99) approving the procedure for providing palliative assistance and nursing care;

100) approval of regulations on the activities of organizations and (or) structural units of healthcare organizations, performing laboratory diagnostics, as well as the volume and types of the researches, carried out by them;

101) approval of regulations on the activities of organizations and (or) structural subdivisions of healthcare organizations, performing pathoanatomical diagnostics, as well as the procedure for performing pathoanatomical autopsy;

102) approval of the procedure for organizing and conducting internal and external expertises of the quality of medical services;

102-1) approval of the procedure for attracting independent experts in conducting an external expertise;

102-2) development and approval of requirements to individuals, applying for carrying out an independent expertise as independent experts;

103) development and approval of the rules for provision of primary health care, as well as attachment to primary health care organizations;

104) development and approval of a standard contract for the provision of medical assistance within the guaranteed volume of free medical care, concluded between the patient and the medical organization;

105) development and approval of methods for the expert evaluation of optimal technical characteristics and clinical and technical substantiation of a medical product;

106) issue of a certificate for a pharmaceutical product (CPP);

107) determining the order of interaction for contractual fractionation;

108) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

109) approval of the first-aid kit for providing first aid;

110) approval of the list of orphan (rare) diseases;

111) approval of the list of medical contra-indications for the conclusion of labor contracts in the field of heavy work, work with harmful and (or) dangerous working conditions, in underground works, and also for admission of persons of the decreed group of the population to work;

112) development and approval of the rules for regulating the price of medicines;

113) development and approval of the rules for the service maintenance of medical devices in the Republic of Kazakhstan;

113-1) reception of notifications on the commencement or termination of activities, defined in subparagraphs 2), 3) and 7) of part one of Article 13-1 of this Code, in the manner, prescribed by the Law of the Republic of Kazakhstan "On permits and notifications", as well as maintenance of the state electronic registry of permissions and notifications;

114) development and approval of the rules for admission of foreign specialists to clinical practice, with the exception of persons, invited to carry out professional medical activities in the National healthcare holding and its subsidiaries, as well as in "Nazarbayev University" or its medical organizations, in medical organizations of the Administration of the President of the Republic of Kazakhstan;

115) development and approval of appropriate pharmaceutical practices;

116) development and approval of rules for the provision of audiological assistance to the population of the Republic of Kazakhstan;

117) excluded by Law of the Republic of Kazakhstan No. 272-VI dated November 25, 2019 (shall be enforced upon expiry of ten calendar days after the day of its first official publication);

118) determining the order of lifetime voluntary donation of tissues (parts of tissue) and (or) organs (parts of organs) after death for transplantation purposes;

119) development and approval of rules for creation of conditions by the employers to undergo preventive medical examinations to persons, subject to these examinations within the guaranteed volume of free medical care and in the system of compulsory social health insurance;

120) development and approval of instructions, algorithms and guidelines for organization of medical assistance;

121) development and approval of the methodology for formation (calculation) of indicators in the field of healthcare;

122) determination of the procedure for procurement of goods and services for examination during the state registration of medicines and medical devices and evaluation of their safety and quality;

122-1) development and approval of rules for the provision of medical assistance to the students and pupils of educational organizations;

122-2) development and approval of the rules for the conduct of a medical examination to establish the use of a psychoactive substance and the state of alcohol intoxication;

122-3) development and approval of rules for the purchase of services from healthcare subjects within the guaranteed volume of free medical care and in the system of compulsory social health insurance;

123) development and approval of the regulation on the activities of medical-consultative commission;

124) development and approval of the size of tariffs for medical services, provided within the guaranteed volume of free medical care financed from the republican budget, as well as the methodology for their formation;

125) development and approval of the rules for the assessment of scientific and pedagogical staff of scientific organizations and educational organizations in the field of health care, the rules for assessing the knowledge and skills of students in medical education programs;

126) development and approval of the rules for provision of information on medical waste ;

127) development and approval of the rules for the dynamic monitoring of patients with chronic diseases.

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); dated 16.05.2014 No. 203-V (shall be enforced upon expiry of six months after its first official publication); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 29. 12. 2014 No. 269-V (shall be enforced from 01.01.2015); dated 06.04.2015 № 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 № 406-V (shall be enforced from 01.07.2017); dated 21. 04. 2016 № 504-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 29. 03. 2016 No. 479-V (shall be enforced upon expiry of twenty-one calendar days after its first official publication); dated 22. 12. 2016 No. 29-VI (shall be enforced from 01.01.2017); dated 30.06.2017 № 80-VI (the procedure of enactment see Article 2); dated 26. 12. 2017 No. 124-VI (shall be enforced from 01.01.2018); dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (the order of enforcement, see Art. 2); dated 19.04.2019 № 250-VI (shall be enforced upon expiry of ten calendar days after the day of its first official publication); No. 272-VI dated November 25, 2019 (shall be enforced upon expiry of ten calendar days after the day of its first official publication);

Article 7-1. Competence of the state body in the field of sanitary and epidemiological welfare of the population

1. The state body in the sphere of sanitary and epidemiological welfare of population shall perform the following functions:

1) implementation of state policy in the sphere of sanitary and epidemiological welfare of population;

2) development and approval within its competence of normative legal acts and forms of accounting and reporting documentation in the field of sanitary and epidemiological welfare of population;

3) development and approval of regulations;

4) implementation of monitoring in the field of sanitary and epidemiological welfare of population;

5) coordination of activities of healthcare organizations, carrying out activities in the field of sanitary and epidemiological welfare of population;

6) provision of departmental statistical supervision in the sphere of sanitary and epidemiological welfare of population;

7) creation and operation of electronic information resources and information systems, information and communication networks in the field of sanitary and epidemiological welfare of population, organization of access of individuals and legal entities to them in accordance with the legislation of the Republic of Kazakhstan on informatization;

8) ensuring the development of science and coordination of scientific activity in the sphere of sanitary-epidemiological welfare of population;

9) concluding of memoranda with the heads of local executive bodies aimed at achieving the final results of activities in the field of sanitary and epidemiological welfare of population;

10) determining the procedure for conducting sanitary and epidemiological expertise;

11) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

12) organization of conducting qualification examinations in the field of sanitary and epidemiological welfare of population;

13) introduction of restrictive measures, including quarantine, with special conditions of economic and (or) other activity and life of population;

14) determining the order of keeping the register of potentially dangerous chemical, biological substances prohibited for the use in the Republic of Kazakhstan;

14-1) identifying the hazard classes of waste in terms of their impact on humans and the environment (in terms of toxicity);

15) implementation of joint international projects in the field of sanitary and epidemiological welfare of population;

16) consideration of applications of individuals and legal entities on the issues of sanitary and epidemiological welfare of population;

17) organization of hygienic training of population;

18) organization and implementation, within its competence, of sanitary and anti-epidemic and sanitary-preventive measures for food poisoning, infectious and other diseases;

19) issue of sanitary-epidemiological conclusions on compliance (non-conformity) of the object of state sanitary-epidemiological control and supervision to normative legal acts in the field of sanitary and epidemiological welfare of population and hygienic standards;

20) implementation of the epidemiological control of infectious and parasitic diseases;

21) consideration of cases on administrative offenses and imposition of administrative penalties in accordance with the Code of the Republic of Kazakhstan on Administrative Offenses;

22) implementation of state sanitary and epidemiological control and supervision on the territory of the Republic of Kazakhstan;

22-1) is excluded by the Law of the Republic of Kazakhstan dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

23) is excluded by the Law of the Republic of Kazakhstan dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

24) is excluded by the Law of the Republic of Kazakhstan dated 27. 02. 2017 No. 49-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

25) determining of a territory or its part, free from diseases or with a low prevalence of diseases;

26) establishment of sanitary-quarantine points at checkpoints across the State border of the Republic of Kazakhstan, coinciding with the customs border of the Eurasian economic union;

27) approval of the list of epidemically significant objects;

28) determining of a unified methodology for all organizations, having the right to conduct a risk assessment, the procedure for conducting a risk assessment;

29) control over the compliance with requirements established by technical regulations;

30) implementation of state control over the activities of healthcare organizations, carrying out activities in the field of sanitary and epidemiological welfare of the population;

31) determining the procedure for attestation of the heads of healthcare organizations, carrying out activities in the field of sanitary and epidemiological welfare of the population;

32) approval of draft normative and technical documentation in the field of food safety, subject to sanitary and epidemiological supervision;

33) coordination of the conformity of processes (stages) of development (creation), production (manufacture), turnover, utilization and destruction of food products, conformity of machines and equipment, materials and products used in the development (creation), production (manufacture), turnover, utilization and destruction, with the requirements established by the legislation of the Republic of Kazakhstan on the safety of food products, with the issuance of a sanitary and epidemiological conclusion;

34) development and approval of the rules of hygienic education for persons of the decreed group of population;

35) determining the procedure for assigning accounting numbers to food production facilities and maintaining their register;

36) reception of notifications on the commencement or termination of activities defined in subparagraph 1) of part one of Article 13-1 of this Code, in the manner, prescribed by the Law of the Republic of Kazakhstan "On Permits and Notifications", as well as maintenance of the state electronic register of permits and notifications;

37) determining the procedure for state registration and re-registration of baby food products, food and biologically active additives, genetically modified objects, dyes, means of disinfection, disinsection and deratization, materials and products in contact with water and food;

38) development and approval of the rules for maintaining a register of products that do not meet the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of the population, hygienic standards and technical regulations, as well as placing this registry on the Internet resource of the state body in the field of sanitary and epidemiological welfare of the population.

2. The state body in the sphere of sanitary and epidemiological welfare of population shall perform other functions stipulated by this Code, other laws of the Republic of Kazakhstan, acts of the President of the Republic of Kazakhstan and the Government of the Republic of Kazakhstan.

Footnote. Chapter 2 is supplemented by Article 7-1 in accordance with the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); as amended by the Law of the Republic of Kazakhstan dated 21. 04. 2016 No. 504-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 29.03. 2016 No. 479-V (shall be enforced upon expiry of twenty-one calendar days after its first official publication); dated 27.02.2017 No. 49-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 26. 12. 2017 No. 124-VI (shall be enforced from 01.01.2018); dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 8. Competence of central executive bodies and other central state bodies with military medical (medical), forensic, forensic and narcological, forensic psychiatric subdivisions

Footnote. The title of Article 8 is in the wording of the Law of the Republic of Kazakhstan dated 29.09.2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Central executive bodies and other central state bodies with military medical (medical), forensic, forensic and narcological, forensic psychiatric subdivisions, within their competence shall:

- 1) implement the state healthcare policy;
- 2) carry out the management of activities of military medical (medical), forensic, forensic and narcological, forensic psychiatric subdivisions;
- 3) approve the order of military-medical (medical) support to the military-medical (medical) subdivisions;
- 4) appoint the heads of military medical (medical), forensic, forensic and narcological, forensic psychiatric subdivisions to posts and dismiss them;
- 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 approve the structure of organizations and subdivisions, regulations on their activities, model staff and staff standards in military medical (medical), forensic, forensic and narcological, forensic psychiatric 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) submit proposals to the state body in the field of sanitary and epidemiological welfare of population on introduction (cancellation) of restrictive measures, including quarantine, on the territory of military medical (medical) units;
- 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.
- 12) approve the Rules for the conduct of military medical expertise and the Regulation on the bodies of military medical expertise.

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 ten calendar days after its first official publication); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 9. Competence of local government bodies of regions, cities of republican significance and the capital

Footnote. The title of Article 9 is in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

1. Local representative bodies of regions, cities of republican significance and the capital:
 - 1) is excluded by the Law of the Republic of Kazakhstan dated 03.07.2013 No. 124-V (shall be enforced upon expiry 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) decide on the additional provision of medicines, specialized medical products, medical devices to certain categories of citizens during outpatient treatment free of charge and (or) on preferential terms;

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, cities of republican significance and the capital:

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

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

3) ensure the implementation by citizens of the Republic of Kazakhstan, oralmans, as well as foreigners and stateless persons permanently residing in the territory of the Republic of Kazakhstan, the right to a guaranteed amount of free medical care and medical care in the system of compulsory social health insurance;

3-1) carry out control of keeping the persons in the centers of temporary adaptation and detoxification centers;

3-2) ensure stability in the activities of healthcare organizations that are municipal legal entities;

3-3) ensure the availability of infrastructure for physical culture and sports, recreation and leisure;

3-4) organize a set of measures to promote a healthy lifestyle;

3-5) take measures for safety and protection of labor, prevention of domestic and road traffic injuries;

3-6) ensure effective planning and use of healthcare resources;

3-7) take measures to improve the quality of medical services;

3-8) provide the population with access to information on health issues;

- 4) implement measures to promote voluntary unpaid donation of blood and its components;
 - 4-1) pay travel within the country for certain categories of citizens according to the list determined by the local representative bodies of regions, cities of republican significance and the capital, who travel outside the settlement of permanent residence to receive specialized medical care using high-tech medical services within the guaranteed volume of free medical care and in the system of compulsory social health insurance;
- 5) create local healthcare government agencies;
 - 5-1) appoint and dismiss the heads of local government health authorities of oblasts, cities of republican significance and the capital in agreement with the authorized body;
- 6) organize control over staffing of public healthcare organizations;
 - 6-1) take measures to ensure the staffing of public health organizations, including measures of social support and consolidation of young specialists;
- 7) take measures to build and develop a network of healthcare organizations, their financial and logistical support, including the development of a state pharmacies network and creation of pharmacy stores;
- 8) coordinate the activities of public and private healthcare sectors;
- 9) ensure the provision of free medical care, medicines and medical products in emergency situations, introduction of a state of emergency;
- 10) conduct inter-regional and international cooperation in healthcare area;
- 11) carry out licensing of medical activities, except for forensic, forensic-narcological, forensic-psychiatric examinations, in accordance with the Law of the Republic of Kazakhstan "On Permits and Notifications";
- 12) provide training, qualification development and retraining of personnel in the field of healthcare;
- 13) conduct the measures needed to improve health, prevent diseases, promote healthy lifestyles and healthy eating;
- 14) organize the provision of medical care to the population, including the prevention and treatment of socially significant diseases and diseases that pose a danger to others, including drug provision within the guaranteed volume of free medical care and in the system of compulsory social health insurance;
- 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) facilitate implementation of the court decision on sending a citizen, sick with tuberculosis to compulsory treatment;

18-1) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

18-2) monitor compliance with the legislation of the Republic of Kazakhstan on permits and notifications for engaging in medical activities;

18-3) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

18-4) conduct preventive disinsection and deratization (with the exception of disinsection and deratization on the territory of natural foci of infectious and parasitic diseases, as well as on the foci of infectious and parasitic diseases);

18-5) carry out training of specialists with medical education for the sale of medicines and medical devices in the settlements remote from the district center through pharmacies in health care organizations that provide primary medical and sanitary, consultative and diagnostic assistance, and mobile pharmacies in the absence of a specialist with a pharmaceutical education;

18-6) conduct attestation for professional competence of specialists in the field of healthcare, specified in paragraph 4 of Article 15 of this Code;

18-7) ensure implementation of measures for the development of voluntary donation of tissue (part of the tissue) and (or) organs (parts of organs);

18-8) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

18-9) develop and approve a regional long-term plan for development of health care infrastructure in coordination with the authorized body;

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); dated 03.07.2013 No.124-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.05.2014 No. 203-V (shall be enforced upon expiry of six months after its first official publication); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of 10 calendar days after its first official publication); dated 29. 03. 2016 No. 479-V (shall be enforced upon expiry of twenty-one calendar days after its

first official publication); dated 30.06.2017 No. 80-VI (the order of enforcement see article 2) ; dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 10. Competence of local state bodies of health care management of regions, cities of republican significance and the capital

Footnote. The title of Article 10 as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 210-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Local state bodies of health care management of regions, cities of republican significance and the capital within their powers shall:

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 of the Republic of Kazakhstan, oralmans, foreigners and stateless persons permanently residing in the territory of the Republic of Kazakhstan with medicines and medical products in the cases provided for by sub-paragraph 5) of paragraph 1 of Article 9 of this Code, and medical assistance within the guaranteed volume of free medical care, including medical services for temporary adaptation and detoxification;

4) organize and carry out monitoring and control of the activities of healthcare subjects, with the exception of healthcare organizations, carrying out activities in the field of sanitary and epidemiological welfare of population;

5) conduct functions of administrators of budgetary healthcare programs;

6) select providers of medical services to provide a guaranteed volume of free medical care and reimbursement of their costs;

7) procure and store medicines, procure pharmaceutical services in the cases provided for by sub-paragraph 5) of paragraph 1 of Article 9 of this Code, within the guaranteed volume of free medical care in the manner, determined by the Government of the Republic of Kazakhstan;

8) organize the procurement of medical devices, non-medical equipment, ambulance transport, as well as overall repairs of public health care 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) organize the provision of free medical care, provision of medicines and medical products in emergency situations

14) organize and coordinate activities for training, qualification development and retraining of personnel in the field of healthcare;

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;

16-1) ensure the organization of work on pharmacovigilance and monitoring of the safety, quality and effectiveness of medical devices by the subjects of health care;

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 of ten 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); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2018); dated 30.06.2017 No. 80-VI (the procedure of enactment see Art. 2); dated 28.12.2018 No. 210-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 10-1. Competence of the authorized body in the field of physical culture and sport on the issues of sports medicine

1. The authorized body in the field of physical culture and sport shall:

1) carry out management of the activities of sports medicine organizations;

2) appoint and dismiss the heads of republican sports medicine organizations;

3) make proposals to the authorized body on introduction (cancellation) of restrictive measures, including quarantine, on the territory of sports medicine organizations;

4) participate in the medical provision of trainings of national teams of the Republic of Kazakhstan on kinds of sport to sports events;

5) ensure the activity of sports medicine organizations;

6) determine the level of physical development of population;

7) develop and approve the procedure for medical examination of athletes to participate in sports competitions;

8) exercise other powers stipulated by this Law, other laws of the Republic of Kazakhstan, acts of the President of the Republic of Kazakhstan and the Government of the Republic of Kazakhstan.

2. The authorized body in the field of physical culture and sport in coordination with the authorized body shall:

1) develop and approve the procedure for medical support and medical assistance to athletes and coaches upon conducting of sporting events, in the period of rehabilitation after intense physical exertion, diseases and injuries of athletes;

2) develop and approve the structure of sports medicine organizations and regulations on their activities.

Footnote. Chapter 2 is supplemented with Article 10-1 in accordance with the Law of the Republic of Kazakhstan dated 03.07.2014 No. 229-V (shall be enforced upon expiry 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 the conduct of preclinical (non-clinical) and clinical studies of medicines and medical devices;

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); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 11-1. Joint commission on the quality of medical services

1. The joint commission on the quality of medical services shall be established with the aim of developing recommendations for the improvement of clinical protocols, standards of medical education, drug provision, quality control system standards and accessibility of healthcare services.

2. The joint commission on the quality of medical services shall be formed from the representatives of state bodies, non-governmental organizations.

3. The procedure for forming a joint commission on the quality of medical services, the regulations on its activities shall be determined by the authorized body.

Footnote. Chapter 2 is supplemented by Article 11-1 in accordance with the Law of the Republic of Kazakhstan dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2017).

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 interaction of state bodies and healthcare organizations in the field of emergency medicine shall be carried out by the authorized body in the field of civil protection

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 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. Is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

8. The integration of information systems of healthcare with information systems of other governmental agencies on the issues of information exchange shall be carried out in accordance with the 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; dated 11.04.2014 No. 189-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 № 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 24.11.2015 № 419-V (shall be enforced from 01.01.2016).

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 the manner prescribed by the legislation of the Republic of Kazakhstan on permits and notifications.

Import to the territory of the Republic of Kazakhstan from countries that are not the members of Eurasian economic union and export from the territory of the Republic of Kazakhstan to these countries of organs (parts of organs) and (or) human tissues, blood and its components, with the exception of hematopoietic stem cells, bone marrow in case of their transfer for the purpose of carrying out unrelated transplantation, as well as samples of cells, tissues, biological fluids and secrets, including human waste products, physiological and pathological excreta, smears, scrapings, washings, intended for diagnostic and research purposes or received in the course of biomedical research, shall be carried out on the basis of licenses, issued by the authorized body.

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); as amended by the Law of the Republic of Kazakhstan dated 26.12.2017 No. 124-VI (shall be enforced from 01.01.2018); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten 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 the decreed groups of population;
- 2) wholesale of medical products;
- 3) retail sales of medical products;
- 4) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);
- 5) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);
- 6) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);
- 7) the conduct of non-interventional clinical studies.

Notification on the commencement or termination of the activity, specified in part one of this Article shall be filed in accordance with the procedure established by the Law of the Republic of Kazakhstan "On Permits and Notifications".

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.); as amended by the laws of the Republic of Kazakhstan dated 16. 05. 2014 No. 203-V (shall be enforced upon expiry of six months after its first official publication); dated 29. 03. 2016 No. 479-V (shall be enforced upon expiry of twenty- one calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 14. Accreditation in healthcare area

1. Subjects of health care shall be subject to the accreditations in the field of health care in order to recognize the compliance of the medical services provided with the established requirements and standards in the field of health care, as well as to assess the professional qualifications and confirm the qualifications of health care specialists, to assess the teaching staff of scientific organizations and educational organizations in the field of health care and to assess the knowledge and skills of students in the programs of medical education.

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 medical organizations shall be carried out on the basis of an external comprehensive assessment of their compliance with accreditation standards, approved by the authorized body, and shall be taken into account when placing the state order for the provision of the guaranteed volume of free medical care and medical assistance in the system of compulsory social health insurance.

Accreditation of testing laboratories carrying out monopolistic activities for examination and evaluation of the safety and quality of medicines and medical devices shall be carried out in the manner, determined by the authorized body.

4. Is excluded by the Law of the Republic of Kazakhstan dated 29.03.2016 No. 479-V (shall be enforced from 01.01.2017).

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), carrying out the accreditation of healthcare subjects, shall establish the appropriate accreditation commissions and form a database of accredited subjects in the field of healthcare.

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); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 № 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 № 406-V (shall be enforced from 01.07.2017); dated 29. 03. 2016 No. 479-V (shall be enforced from 01.01.2017); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 15. Attestation of professional competence of specialists in the field of healthcare

1. Attestation of professional competence of specialists in the field of healthcare (hereinafter - attestation) shall be a periodically performed procedure for determining the level of professional competence of the heads of local bodies of state healthcare authorities of oblasts, cities of republican significance and the capital and also their deputies, heads of healthcare organizations subordinate to the authorized body, their deputies, heads of branches, heads of healthcare organizations, subordinate to local bodies of state healthcare authorities of oblasts, cities of republican significance and the capital, heads of healthcare organizations, carrying out activities in the field of sanitary and epidemiological welfare of population.

2. Attestation commissions shall be established for the objective and competent implementation of attestation by the authorized body, local public healthcare authorities of oblasts, cities of republican significance and the capital, as well as by the state body in the sphere of sanitary and epidemiological welfare of population.

3. The authorized body shall conduct the attestation of the heads of local state healthcare authorities of oblasts, cities of republican significance and the capital and their deputies, the heads of organizations subordinate to the authorized body, their deputies, and the heads of branches.

4. Local bodies of state healthcare authorities of oblasts, cities of republican significance and the capital shall conduct the attestation of the heads of healthcare organizations subordinate to them.

5. The attestation of the heads of healthcare organizations, carrying out activities in the field of sanitary and epidemiological welfare of the population shall be conducted by the state body in the field of sanitary and epidemiological welfare of population.

6. The attested persons shall undergo attestation at the end of each subsequent three years, but not earlier than one year from the day of the respective position.

Footnote. Article 15 is in the wording of the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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 in the field of circulation of medicines and medical devices;
- 5) standards for organization of medical assistance provision;
- 6) standards of informatization in the field of healthcare.

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

Footnote. Article 16 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 17. Confirmation of conformity of goods (works, services) in the field of healthcare

Confirmation of compliance of goods (works, services) in the field of health care, except for the medicines and medical devices, shall be made in order to determine their safety for human life and health and shall be carried out in accordance with the legislation of the Republic of Kazakhstan in the field of technical regulation.

Footnote. Article 17 is in the wording of the Law of the Republic of Kazakhstan dated 29.10.2015 No. 376-V (shall be enforced from 01.01.2016); as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 18. Advertising in healthcare area

1. Advertising of medicines and medical products shall be carried out in the manner determined by the authorized body.

Advertising of biologically active food additives shall be carried out in the manner determined by the state body in the field of sanitary and epidemiological welfare of the population.

2. Advertising of medical services, methods and means of prevention, diagnosis, treatment and medical rehabilitation (hereinafter referred to as the services), medicines and medical devices, biologically active food additives should be reliable, recognizable without special knowledge or use of special tools, should exclude comparisons with other services, medicines and medical products, biologically active food additives, should not mislead

consumers by abusing their trust, including in respect of the characteristics, composition, consumer properties, cost (price), the proposed outcome of the use, the results of research and testing.

3. It shall be prohibited:

1) advertising of medicines and medical products, dietary supplements, prophylactic agents 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) the use of children, their images and voices in the advertising of medicines and medical devices, except for medicines and medical products for children;

4) distribution and placement of advertising of medicines and medical products, dietary supplements in public transport, organizations not related to their purpose, use and release, except for the advertising of medicines at medical, pharmaceutical conferences, congresses, symposia and other scientific meetings;

4-1) placement of advertising information on industrial products, prescription forms;

5) placement of outdoor (visual) advertising of medicines and medical products;

6) the use of medical personnel authorized to prescribe medicines and medical devices as advertising distributors, except for the cases of providing reliable information about medicines and medical devices for scientific or educational purposes, as well as to inform patients;

7) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

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.

9) indication in advertising for the population of the following diseases: sexually transmitted diseases, oncological, mental, dangerous infectious diseases, HIV infection, tuberculosis, diabetes mellitus;

10) in the advertising, to refer to the recommendations of scientists, health care specialists , as well as the state bodies' officials who can encourage the use and (or) prescription of medicines and medical devices;

11) in the advertising to present services, medicines and medical products, biologically active food additives as unique, the most safe and effective;

12) assert that the safety and efficacy of a medicinal product is due to its natural origin;

13) suggest that the effectiveness of the provided service, the treatment with the advertised medical product, biologically active additive to food shall be guaranteed, the use of the medicine shall not be accompanied by development of side effects;

14) in the advertising to bring information that is not directly related to the advertised service, medicine and medical device;

15) advertisement of offers on fulfillment of illegal transactions concerning tissues (a part of a tissue) and (or) bodies (a part of bodies) of the person.

4. Is excluded by the Law of the Republic of Kazakhstan dated 16. 05. 2014 No. 203-V (shall be enforced upon expiry of six months after its first official publication).

5. Distribution and placement of advertising of services, medicines and medical devices shall be allowed in periodicals, other media and health care organizations.

5-1. Advertisement of medicines should contain complete (including appropriate restrictions for the use of the medicine) and reliable information, exclusion of which may lead to inappropriate use of medicines or unjustified risk to the consumer.

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); dated 16.05.2014 No. 203-V (shall be enforced upon expiry of six months after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 21. 04. 2016 No. 504-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Chapter 5. State control and supervision in the field of health care

Footnote. The title of Chapter 5 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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 medicines and medical devices.

3. State control and supervision in the field of health care shall be carried out in the form of inspection and preventive control and supervision.

Inspection and preventive control and supervision with a visit to the subject (object) of control and supervision shall be carried out in accordance with the Business Code of the Republic of Kazakhstan.

Preventive control and supervision without visiting the subject (object) of control and supervision shall be carried out 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. Is excluded by the Law of the Republic of Kazakhstan dated 29.12.2014 No. 269-V (shall be enforced from 01.01.2015).

6. In assessing the degree of risks of objects, subject to state sanitary and epidemiological surveillance, in addition to the criteria provided by the Entrepreneurial Code of the Republic of Kazakhstan, the set of the following qualitative indicators, related to the immediate activity of the audited subject shall be taken into account:

results of previous inspections;

organization and implementation of production control;

conducting of an initiative audit in the field of sanitary and epidemiological welfare of population.

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); dated 29. 12. 2014 No. 269-V (shall be enforced from 01.01.2015); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 29.10.2015 № 376-V (shall be enforced from 01.01.2016); dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten 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. State control in provision of medical services shall be carried out in the form of verification and preventive control in accordance with the Business Code of the Republic of Kazakhstan.

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 main state inspectors for control in provision of medical services of regions, cities of republican significance and the capital, their deputies;

4) state inspectors for control in provision of medical services in regions, cities of republican significance 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 for control in provision of medical services of the Republic of Kazakhstan shall be entitled to issue an order to the head of the local state body of health care management of the region, the city of republican significance, the capital based on the results of the inspection.

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;

5-1) initiate the creation of a commission with the involvement of independent experts to analyze cases for carrying out external expertise, determined by the authorized body;

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.); dated 29.10.2015 No. 376-V (shall be enforced from 01.01.2016); dated 29. 03. 2016 No. 479-V (shall be enforced from 01.01.2017); dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 210-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 21. State sanitary and epidemiological control and supervision

1. State sanitary and epidemiological control and supervision shall be aimed at preventing, identifying, suppressing violations of the legislation of the Republic of Kazakhstan in the field of sanitary and epidemiological welfare of population, as well as monitoring compliance with regulatory legal acts in sanitary and epidemiological welfare of population, hygienic standards and technical regulations to protect the health and environment of the population and the safety of products, processes, services.

2. The state body in the sphere of sanitary and epidemiological welfare of population shall determine the procedure for implementation of sanitary and quarantine control over the delivery and spread of infectious and parasitic diseases on the State border of the Republic of Kazakhstan coinciding with the customs border of the Eurasian economic union and ensuring sanitary protection of the State border and the territory of the Republic of Kazakhstan.

3. The objects of state sanitary and epidemiological control and supervision shall be individuals and legal entities, buildings, facilities, products, equipment, vehicles, soil, water, air, food and other objects, functioning, use, consumption, application and exploitation of which may harm the state of human health and environment.

Objects of state sanitary and epidemiological control and supervision (epidemically significant objects) shall be divided into two groups:

- 1) objects of high epidemiological significance;
- 2) objects of low epidemiological significance.

The list of products and epidemiologically significant objects that are subject to the state sanitary and epidemiological control and supervision shall be approved by the state body in the field of sanitary and epidemiological welfare of the population in coordination with the authorized bodies on entrepreneurship and in the field of environmental protection within their competence.

4. State sanitary and epidemiological control and supervision shall be carried out in the form of inspection and preventive control and supervision.

Inspection and preventive control and supervision with a visit to the subject (object) of control and supervision shall be carried out in accordance with the Business Code of the Republic of Kazakhstan.

Inspections in respect of objects of high epidemiological significance shall be carried out in a special order with a frequency based on a risk assessment system in accordance with the Business Code of the Republic of Kazakhstan.

Exemption of objects of high epidemiological significance from inspections, conducted in a special manner, shall be carried out in accordance with the criteria for assessing the degree of risk, determined by the authorized body together with the authorized body on entrepreneurship.

For objects of minor epidemiological significance, only unscheduled inspections shall be conducted.

5. The monitoring of product safety shall be a preventive control and supervision and shall be carried out through:

- 1) a cameral control;
- 2) a selection and conduct of sanitary and epidemiological examination of products.

6. Cameral control shall be carried out on the basis of studying and analyzing information about participants in external economic activities, applicants, applying for the test, confirming the conformity of products or registering a declaration of conformity of products, recognizing the results of conformity assessment, the test results, as well as containing in other documents, presented as evidences of the conformity of products submitted, to the state body in the sphere of sanitary-epidemiological welfare of the population by the customs authorities, the authorized body in the field of technical regulation.

The objects of cameral control shall be the participants of external economic activity, the conformity assessment bodies, testing laboratories (centers), subjects of private entrepreneurship, declaring the conformity of products with the requirements of the legislation of the Republic of Kazakhstan.

The list of information necessary for implementation of cameral control, as well as the procedure for their presentation by the customs authorities, the authorized body in the field of technical regulation, the conformity assessment bodies and testing laboratories (centers) shall be determined by the state body in the field of sanitary and epidemiological welfare of population.

7. Information on the participants in external economic activities, on products imported and documents confirming the conformity of the imported products shall be submitted by the customs authorities.

Information on applicants, applying for carrying out the test, confirming the conformity of products or registering the declaration of conformity of products, recognizing the results of conformity assessment, test results, as well as containing in other documents presented as evidences of conformity of products, shall be submitted by the authorized body in the field of technical regulation, conformity assessment bodies and testing laboratories (centers).

8. The state body in the field of sanitary and epidemiological welfare of population based on the results of cameral control in detecting the violations of the requirements of regulatory

legal acts in the sphere of sanitary and epidemiological welfare of population, hygienic standards and technical regulations, as well as on the basis of analysis of the comparison of information between imported products and issued, registered, recognized documents on the confirmation of conformity for the imported products, in respect of subjects of cameral control shall take the following measures:

1) an instruction to eliminate violations of the requirements of regulatory legal acts in the sphere of sanitary and epidemiological welfare of population, hygienic standards and technical regulations with mandatory explanation of the procedure for its elimination shall be sent to the addresses of participants of external economic activities and subjects of private entrepreneurship declaring the conformity of products with the requirements of the legislation of the Republic of Kazakhstan engaged in importation and (or) realization of products on the territory of the Republic of Kazakhstan;

2) information, indicating the facts of violation of the requirements of the legislation of the Republic of Kazakhstan in the field of technical regulation shall be sent to the authorized body in the field of technical regulation.

9. Selection and sanitary-epidemiological expertise of products shall be conducted to identify and prevent violations of the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of population, hygienic standards and technical regulations.

Selection of products for sanitary and epidemiological examination shall be carried out by the officials of the state body in the field of sanitary and epidemiological welfare of population and shall be certified by a document, confirming the fact of purchase of the product.

The state body in the sphere of sanitary and epidemiological welfare of population, if it finds out products that do not meet the requirements of the legislation of the Republic of Kazakhstan on the basis of the results of sanitary epidemiological expertise, shall take the measures specified in paragraph 8 of this Article, except for cases of identifying products dangerous to life, human health and the environment, in relation to which an unscheduled inspection of objects shall be carried out in accordance with the Entrepreneurial Code of the Republic of Kazakhstan.

10. Control of implementation of instructions to eliminate violations of the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of population, hygienic standards and technical regulations shall be carried out during an unscheduled inspection in accordance with the Entrepreneurial Code of the Republic of Kazakhstan by the state body in the field of sanitary and epidemiological welfare of population.

11. The officials of sanitary and epidemiological service, authorized in accordance with this Code to carry out state sanitary and epidemiological control and supervision shall be:

1) The Chief state sanitary doctor of the Republic of Kazakhstan and his deputies, the chief state sanitary doctors on the relevant territories and transport, their deputies, determined

by the head of the state body in the field of sanitary and epidemiological welfare of population;

2) the heads, their deputies and specialists of the state body in the field of sanitary and epidemiological welfare of population;

3) the heads, their deputies and specialists of territorial subdivisions of the state body in the sphere of sanitary and epidemiological welfare of population on the respective territories and transport;

4) the heads and specialists of structural subdivisions of the Ministry of Defense of the Republic of Kazakhstan, national security and internal affairs bodies, departments of the Administration of the President of the Republic of Kazakhstan, carrying out activities in the field of sanitary and epidemiological welfare of population.

12. Officials of sanitary and epidemiological Service, authorized in accordance with this Code to exercise state sanitary and epidemiological control and supervision shall have the right to:

1) prohibit importation, use and realization on the territory of the Republic of Kazakhstan, including on epidemically significant objects, of products intended for the use and applying by the population, as well as in entrepreneurial and (or) other activities, with:

non-compliance with sanitary and epidemiological requirements and requirements of technical regulations;

absence of a document, certifying the safety, issued by the state body in the sphere of sanitary and epidemiological welfare of population;

absence of a sanitary and epidemiological conclusion (during exploitation or use of the object, vehicle subject to state sanitary and epidemiological control);

detection of falsified products;

unidentified expiration date and (or) storage, expired shelf life and (or) storage;

detection of insects, rodents and traces of their stay in the product itself;

creation of a threat of the emergence and spread of infectious diseases or mass non-infectious diseases and poisonings, including its recognition as dangerous to the health and environment of the population based on the results of sanitary and epidemiological expertise;

2) prohibit the production of products intended for use, applying by the population, as well as in entrepreneurial and (or) other activities, with:

non-compliance of objects and production technology with sanitary and epidemiological requirements and requirements of technical regulations;

absence of a sanitary and epidemiological certificate for the production object;

absence of the production equipment necessary for the observance of technological process of product production, industrial and technological equipment, apparatus, inventory;

absence of state registration for the first time introduced into production and previously unused substances and materials and preparations on their basis that are dangerous to the population;

absence of a sanitary-epidemiological conclusion for new products, technology, equipment;

use of prohibited food additives, ingredients and raw materials;

creation of the threat of the emergence and spread of infectious diseases or mass non-infectious diseases and poisonings;

absence of a veterinary and sanitary certificate at the object for the production of livestock products;

3) prohibit or suspend the use of baby food, food and biologically active food additives, genetically modified objects, materials and products in contact with water and food, chemicals, certain types of products and substances harmful to human health;

4) call individuals, officials and legal entities to consider the facts of violation of the legislation of the Republic of Kazakhstan in the field of sanitary and epidemiological welfare of population to the bodies of the sanitary and epidemiological service;

5) make decisions on temporary suspension from work of persons, belonging to the decreed groups of the population that are the source of infectious and parasitic diseases, as well as those who did not pass mandatory medical examinations in time, until getting the result of a laboratory test and the conclusion of a specialist, confirming complete sanitation and compulsory medical examination;

6) establish restrictive measures, including quarantine at certain sites, in the manner determined by the state body in the field of sanitary and epidemiological welfare of population;

7) direct the persons, who are the potential sources of spreading of infectious and parasitic diseases, and having been in contact with infectious patients to a medical examination with their exclusion from work until getting the laboratory examination results, confirming the complete sanitation;

8) direct the persons who are the sources of infectious and parasitic diseases to hospitalization on indications;

9) demand mandatory vaccination of population, preventive and focal disinfection, disinfestation and deratization in premises and vehicles, territories, in foci of infectious and parasitic diseases;

10) suspend certain types of works, operation of existing, constructing or reconstructing facilities in accordance with the Code of the Republic of Kazakhstan on Administrative Offenses until the violation of regulatory legal acts in the sphere of sanitary and epidemiological welfare of population and hygienic standards is eliminated;

11) prohibit the production, application and sale of new types of raw materials, products, chemicals, technological equipment, mechanisms, processes, tools in case of their recognition as hazardous to human life and health;

12) request materials, necessary for studying the assessment of impact of the object of expertise on the environment and public health, as well as to take samples and to select samples of products in quantities sufficient and not exceeding the required volumes for its conduct, without compensation for the cost of these products to conduct sanitary and epidemiological expertise;

13) make demands for bringing legal acts affecting sanitary and epidemiological welfare of population in accordance with the legislation of the Republic of Kazakhstan in the sphere of sanitary and epidemiological welfare of population;

14) carry out radiation monitoring in the sphere of sanitary and epidemiological welfare of population on the territory of the Republic of Kazakhstan;

15) establish sanitary protection zones and change their sizes;

16) is excluded by the Law of the Republic of Kazakhstan dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

17) apply to the court in case of failure or improper fulfillment by individuals and legal entities of legal requirements or orders, decisions, issued by the officials of the sanitary-epidemiological service;

18) suspend the license for sanitary-hygienic and anti-epidemic medical activities in accordance with the Code of the Republic of Kazakhstan on Administrative Offenses;

19) is excluded by the Law of the Republic of Kazakhstan dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

20) involve specialists of healthcare organizations in implementation of sanitary and anti-epidemic and sanitary-preventive measures at infectious and parasitic diseases, poisoning of population.

13. For taking decision on the results of state sanitary and epidemiological control and supervision, depending on the established violations of the requirements of the legislation of the Republic of Kazakhstan in the sphere of sanitary and epidemiological welfare of population, the following acts shall be issued by the officials of sanitary and epidemiological service:

1) an act of sanitary-epidemiological examination - a document, issued by an official carrying out state sanitary and epidemiological control and supervision, based on the results of inspection of the object for its compliance with the requirements of the legislation of the Republic of Kazakhstan in the field of sanitary and epidemiological welfare of population;

2) an order on eliminating violations of the requirements of the legislation of the Republic of Kazakhstan in the field of sanitary and epidemiological welfare of population;

3) a decision of the Chief state sanitary doctor of the Republic of Kazakhstan on imposing disciplinary punishment to the heads of state bodies and organizations of sanitary-epidemiological service;

4) decisions of the chief state sanitary doctors on:

conducting sanitary and anti-epidemic and sanitary-preventive measures;

temporary suspension of individuals from work;

prohibition of importation, production, use and realization of products intended for the use and consumption by the population, as well as in business and (or) other activities;

prohibition of production, use and realization of new types of raw materials, products, chemicals, technological equipment, mechanisms, processes, tools in case of their recognition as hazardous to human life and health;

suspension of activities or certain types of activities of an individual entrepreneur or legal entity in accordance with the Code of the Republic of Kazakhstan on Administrative Offenses

14. Citizens of the Republic of Kazakhstan, having higher medical education of sanitary-epidemiological profile shall be appointed to the posts of the heads of state bodies and organizations of sanitary-epidemiological service.

Footnote. Article 21 is in the wording of the Law of the Republic of Kazakhstan dated 29.12.2014 No. 269-V (shall be enforced from 01.01.2015); as amended by the laws of the Republic of Kazakhstan dated 29. 10. 2015 No. 376-V (see Article 2 for the procedure of enactment); dated 04.21.2016 № 504-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 10.02.2017 No. 45-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 26. 12. 2017 No. 124-VI (shall be enforced from 01.01.2018); dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 21-1. Permissions and notifications in the field of sanitary and epidemiological welfare of population

1. The state body in the sphere of sanitary and epidemiological welfare of population in accordance with the Law of the Republic of Kazakhstan "On Permits and Notifications" shall issue the following permitting documents:

1) is excluded by the Law of the Republic of Kazakhstan No. 49-VI dated 27. 02. 2017 (shall be enforced upon expiry of ten calendar days after its first official publication);

2) a sanitary and epidemiological opinion on the compliance of the object of high epidemic significance with the requirements of regulatory legal acts in the field of sanitary and epidemiological well-being of the population and hygienic standards;

3) sanitary and epidemiological conclusion on the agreement of expiration dates and conditions for the storage of food products;

4) certificate of state registration or re-registration of baby food products, food and biologically active food additives, genetically modified objects, dyes, means of disinfections, disinsection and deratization, materials and products in contact with water and food, chemicals, certain types of products and substances, having a harmful effect on human health;

5) is excluded by the Law of the Republic of Kazakhstan dated 29.03.2016 No. 479-V (shall be enforced upon expiry of twenty-one calendar days after its first official publication);

6) permission to work with microorganisms of the I-IV pathogenicity group and helminths

7) is excluded by the Law of the Republic of Kazakhstan dated 29.03.2016 No. 479-V (shall be enforced upon expiry of twenty-one calendar days after its first official publication).

2. It is prohibited to operate objects of high epidemiological significance without a sanitary and epidemiological conclusion on the compliance of the object with regulatory legal acts in the field of sanitary and epidemiological welfare of the population and hygienic standards.

3. The activity (exploitation) of objects of low epidemiological significance shall be carried out without obtaining a sanitary-epidemiological conclusion on the object.

Individuals and legal entities shall be obliged to notify the state body in the sphere of sanitary and epidemiological welfare of population about the beginning and termination of the activity (exploitation) of the object of low epidemiological significance in the order, established by the Law of the Republic of Kazakhstan "On Permits and Notifications".

In this case, individuals and legal entities before the beginning of the activity (exploitation) of objects of low epidemiological significance shall be obliged to bring the object in accordance with the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of population and hygienic standards.

4. Period of validity of permits shall be established by the Law of the Republic of Kazakhstan "On Permits and Notifications".

Permits in the field of sanitary and epidemiological welfare of the population shall be inalienable.

In case of failure to implement the order to eliminate violations of the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of the population, hygienic standards and technical regulations, the officials of the sanitary and epidemiological service shall suspend the permit document on the grounds and in the manner, provided for by this Code and other laws of the Republic of Kazakhstan.

In case of failure to submit an application for elimination of violations by the owner of the permit before the expiry of the suspension of the permit in the field of sanitary and epidemiological welfare of the population, the officials in the field of sanitary and epidemiological welfare of the population within ten working days from the moment of expiration of the specified period shall initiate deprivation (withdrawal) of the permit through legal action.

Re-issuance of permits shall be allowed without additional or repeated research (testing) in the following cases:

- 1) identifying errors in the document (typos);
- 2) re-registration of an individual entrepreneur-applicant, change of his name or legal address;
- 3) changes in the name and (or) location of the legal entity-applicant, manufacturer of the product;
- 4) changes in the address of the location of the object without its physical movement;
- 5) publication of a new regulatory legal act, containing requirements for products, whose adoption does not entail amending the indicators of hygienic safety, the composition of products.

Footnote. Chapter 5 is supplemented with Article 21-1 in accordance with the Law of the Republic of Kazakhstan dated 29.12.2014 No. 269-V (shall be enforced from 01.01.2015); as amended by the laws of the Republic of Kazakhstan dated 29. 03. 2016 No. 479-V (shall be enforced upon expiry of twenty-one calendar days after its first official publication); dated 27.02.2017 No. 49-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 21-2. Procedure for consideration of complain by appeal commission

1. Acts on the inspection results, issued by the officials exercising state sanitary and epidemiological control and supervision may be appealed to a higher authority.

2. For consideration of a complaint on the act on the inspection results, the higher state body shall establish an appeal commission, which must include representatives of the state body in the field of sanitary and epidemiological welfare of the population and the National Chamber of Entrepreneurs of the Republic of Kazakhstan.

The regulations, the provision and composition of the appeal commission shall be determined by the state body in the field of sanitary and epidemiological welfare of the population.

3. The complaint against the act on the inspection results of the state body in the field of sanitary and epidemiological welfare of the population shall be considered by the appeal commission within the limits of the issues being appealed.

4. The complaint against the act on the inspection results shall be submitted in writing in the manner and time provided for by the legislation of the Republic of Kazakhstan.

5. The decision of the appeal commission shall be a recommendation.

6. The appeal commission shall annually summarize the results of consideration of complaints about the act on the inspection results and make recommendations on improvement of the legislation of the Republic of Kazakhstan.

7. The results of the consideration of the complaint about the act on the inspection results by the appeal commission shall not prevent the complaint from being sent to the court.

8. Appeal to the court in the manner, prescribed by the laws of the Republic of Kazakhstan, shall suspend the consideration of a complaint against an act on the inspection results by the appeal commission until a court decision is made.

Footnote. Chapter 5 shall be supplemented by Article 21-2 in accordance with the Law of the Republic of Kazakhstan dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 21-3. Ensuring confidentiality of information during consideration of complaint by appeal commission

Information constituting a commercial and other secrets protected by law, as well as confidential information shall be submitted to the members of the appeal commission when considering a complaint against an act on the inspection results in the manner determined by the state body in the field of sanitary and epidemiological welfare of the population without obtaining a written permission from the person who filed the complaint.

The above information shall not be subject to disclosure by members of the appeal commission.

Footnote. Chapter 5 shall be supplemented by Article 21-3 in accordance with the Law of the Republic of Kazakhstan dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 22. State control in the field of circulation of medicines and medical devices

Footnote. The title of Article 22 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

1. The state control in the field of circulation of medicines and medical devices shall be aimed at preventing, identifying, suppressing violations, as well as monitoring of compliance with regulatory legal acts, regulating the circulation of medicines and medical devices in the Republic of Kazakhstan.

2. The objects of state control in the field of circulation of medicines and medical devices shall be the individuals and legal entities, engaged in pharmaceutical activities, as well as legal entities carrying out quality control of raw materials, medicines and medical devices.

3. State control in the field of circulation of medicines and medical products shall be carried out in the form of inspection and preventive control in accordance with the Business Code of the Republic of Kazakhstan.

4. The officials exercising the state control in the field of circulation of medicines and medical devices 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 exercising the state control over the circulation of medicines and medical devices should be the citizens of the Republic of Kazakhstan who have a higher pharmaceutical education.

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

1) to withdraw samples of medicines and medical devices in accordance with the legislation of the Republic of Kazakhstan.

2) to prohibit the importation, production, manufacture, storage, use and sale on the territory of the Republic of Kazakhstan of medicines and medical devices that have become unusable, expired, forged medicinal products and medical devices and other products that do not meet the requirements of the legislation of the Republic of Kazakhstan in the field of health care;

3) to issue prescriptions on elimination of violations in the field of circulation of medicines and medical devices;

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 of 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 facilities in the field of circulation of medicines and medical devices for compliance with the requirements of the legislation of the Republic of Kazakhstan;

8) to receive information, departmental reporting on circulation of medicines and medical devices from the subjects in the field of circulation of medicines and medical devices.

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.); as amended by the laws of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 29.10.2015 No. 376-V (shall be enforced from 01.01.2016); dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 22-1. Pharmaceutical inspectorate in the field of medicines

Footnote. Chapter 5 is supplemented with Article 22-1 in accordance with the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten

calendar days after its first official publication); is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry 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;
- 1-1) the assets of social health insurance fund;
- 2) means of voluntary medical insurance;
- 3) the funds received for rendering of the paid services;
- 3-1) funds, received as voluntary donations from individuals and legal entities;
- 4) other sources, not contradicting the legislation of the Republic of Kazakhstan.

2. The procedure and methodology for formation of tariffs for medical services, provided within the guaranteed volume of free medical care and in the system of compulsory social health insurance shall be determined by the authorized body.

Tariffs for medical services provided within the guaranteed volume of free medical care and in the system of compulsory social health insurance shall be approved by the authorized body.

3. Is excluded by the Law of the Republic of Kazakhstan dated 30.06.2017 No. 80-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Footnote. Article 23 as amended by the laws of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2017); dated 30.06.2017 No. 80-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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

Footnote. Title of Article 24 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Financing of healthcare subjects, providing 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 subjects, with the exception of state institutions, on a contractual basis with administrators of budget programs and (or) a fund for social health insurance.

Footnote. Article 24 as amended by the laws of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2018).

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

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

1) payment for services of healthcare subjects within the guaranteed volume of free medical care;

1-1) payment for the services of healthcare entities for the provision of medical care in the system of compulsory social health insurance;

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) the acquisition of medicines, orphan (rare) medicines, blood and its components, vaccines and other immunological medicines (immuno-biological medicines), as well as medical products;

5) elimination of cases and epidemics of infectious diseases;

6) training, qualification development and retraining of personnel in the field of healthcare;

7) development and introduction of medical science achievements;

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

2. Is excluded by the Law of the Republic of Kazakhstan dated 30.06.2017 No. 80-VI (shall be enforced from 01.01.2018).

3. Payment for services of healthcare subjects shall be carried out taking into account the results of monitoring contractual obligations on the quality and volume of medical services in the manner determined by the authorized body.

4. Payment of the cost of pharmaceutical services to the subjects in the field of circulation of medicines and medical devices shall be carried out by administrators of budget programs or a social health insurance fund in the manner, determined 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); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 № 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); No. 80-VI dated June 30, 2017 (see Art. 2 for the enactment procedure); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry 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 healthcare shall 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 confidentiality of electronic information resources of healthcare;

6) confidentiality of electronic information resources, containing personal information 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); dated 24.11.2015 No. 419-V (shall be enforced from 01.01.2016).

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 be 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 data of individuals (patients) shall be provided for implementation of medical activities stipulated by subparagraphs 1), 2), 3), 4), 5), 7) and 8) of Article 37 of this Code.

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); as amended by the Law of the Republic of Kazakhstan dated 06. 04. 2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 28-1. National health care accounts

1. National health care accounts shall be a system of regular, comprehensive and consistent monitoring of financial flows in a country's health care system, used to assess the distribution of health care resources with a view to equal and effective distribution between the measures, aimed at preventing diseases and treating the population.

2. National health care accounts shall be compiled annually on the basis of an international methodology using:

statistical bulletins of the authorized body in the field of state statistics;

data of the central authorized body for budget execution;

data of local authorized bodies on budget execution in the context of medical organizations;

statistical data published on the official Internet resources of the National Bank of the Republic of Kazakhstan, the World Health Organization and the Organization for Economic Cooperation and Development.

Based on the data specified in part one of this paragraph, the authorized body shall generate an analytical report describing expenses in the context of services and providers of medical services, as well as information on the sources of their funding.

3. The procedure for formation and use of the data of the national health care accounts shall be determined by the authorized body.

Footnote. Chapter 7 shall be supplemented by Article 28-1 in accordance with the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after 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) interstate cooperation in the sphere of training, qualification development and retraining of personnel in the field of healthcare;
 - 8) provision of international healthcare assistance in emergency situations;
 - 9) the exchange of information, technologies in the field of circulation of medicines and medical devices and harmonization of requirements for the safety and quality of pharmaceutical and medical products;
 - 10) healthcare protection of the borders, safety of the imported products.

Footnote. Article 29 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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) healthcare organizations, carrying out activities in the field of healthy lifestyle, healthy nutrition;
 - 14) health care organizations carrying out activities in the field of HIV prevention;
14-1) is excluded by the Law of the Republic of Kazakhstan dated 03 .07. 2014 No. 229-V (shall be enforced upon expiry of ten calendar days after its first official publication);
 - 15) national holdings.
 - 16) organizations, carrying out an assessment of professional preparedness and confirmation of compliance of healthcare specialists' qualification.

17) organizations of healthcare for orphans, children left without parental care, from birth to three years, children with mental and physical development defects from birth to four years , carrying out psychological and pedagogical support for the families with the risk of abandoning the child.

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) standards of provision of regions with medical workers;
- 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.); dated 03.07.2014 No. 229-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 33. Organization of medical assistance

1. A medical care shall be organized by an authorized body, local bodies of state management of health care of regions, cities of republican significance and the capital, and medical care - by health care subjects in the manner established by this Code.

2. Healthcare subjects shall provide:

- 1) provision of quality medical care;
- 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) carrying out measures for prevention, caution, diagnosis and treatment of diseases that pose a danger to others, as well as professional 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) information to the authorized body about the cases of infectious diseases, poisonings, mental and behavioral disorders (diseases) that are dangerous for others, to the authorized body in the field of civil protection - about the threat of occurrence and (or) emergence of medical and sanitary consequences of emergencies, to internal affairs bodies - information about people, having applied to fresh injuries, wounds, criminal abortions, cases of diseases that are dangerous to others.

3. The subjects of healthcare in provision of medical care shall be guided by clinical protocols.

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); dated 11.04.2014 No. 189-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 03.12.2015 No. 433-V (shall be enforced from 01.01.2016); dated 28.12.2018 No. 210-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 33-1. The capacity of medical care

Medical assistance shall be provided in the following volumes:

1) the minimum, which is a guaranteed amount of free medical care provided in accordance with Article 34 of this Code;

2) basic, which is medical care in the system of compulsory social health insurance, provided in accordance with the Law of the Republic of Kazakhstan "On Compulsory Social Health Insurance";

3) additional capacity of medical care, including:

medical assistance within the framework of voluntary medical insurance in accordance with the Law of the Republic of Kazakhstan "On Insurance Activities";

medical care provided through the provision of paid services and other sources that do not contradict the legislation of the Republic of Kazakhstan.

Footnote. Chapter 9 is supplemented by Article 33-1 in accordance with the Law of the Republic of Kazakhstan dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2016); as amended by Law of the Republic of Kazakhstan No. 208-VI dated December 28, 2018 (shall be enforced since January 1, 2020).

Article 34. The guaranteed volume of free medical care

1. The guaranteed volume of free medical care shall be provided to citizens of the Republic of Kazakhstan, oralmans, foreigners and stateless persons permanently residing in the territory of the Republic of Kazakhstan, at the expense of budgetary funds, including preventive, diagnostic and therapeutic medical services with the greatest proven effectiveness, as well as medical care.

The list of the guaranteed volume of free medical care shall be approved by the Government of the Republic of Kazakhstan.

2. Medical care included in the guaranteed volume of free medical care shall be provided on the basis of clinical protocols by medical workers admitted to clinical practice in the territory of the Republic of Kazakhstan.

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

1) emergency medical aid ;

2) air ambulance ;

3) primary health care :

preventive vaccinations against infectious and parasitic diseases according to the list determined by the Government of the Republic of Kazakhstan;

preventive medical examinations of target groups of the population, established by the authorized body, with the exception of persons specified in the Law of the Republic of Kazakhstan "On Compulsory Social Health Insurance";

patronage of children under one-year-old;

pregnancy monitoring and family planning;

dynamic observation of patients with chronic diseases according to the list determined by the authorized body;

medical and social assistance for socially significant diseases according to the list determined by the authorized body;

emergency medical care;

reception, consultation with a specialist in primary health care, including in acute or exacerbation of chronic diseases;

diagnostic services, including laboratory diagnostics, according to the list determined by the authorized body;

consultation of patients on healthy lifestyles, reproductive health, and family planning;

4) consultative and diagnostic assistance in the direction of a primary health care specialist and specialized specialists:

medical and social assistance to persons suffering from socially significant diseases, including their dynamic observation;

reception and consultation by specialized specialists of persons with chronic diseases subject to dynamic observation;

diagnostic services, including laboratory diagnostics, according to the list determined by the authorized body;

5) hospital-replacing medical care for:

treatment of socially significant diseases;

treatment of chronic diseases subject to dynamic observation;

carrying out medical and diagnostic measures in the admission department of the hospital until a diagnosis is established that does not require treatment in a 24-hour hospital;

6) inpatient medical care, including treatment:

patients hospitalized for urgent indications;

socially significant diseases;

infectious diseases and diseases that pose a danger to others, according to the list determined by the authorized body;

chronic diseases subject to dynamic observation;

7) provision of blood products and blood components for medical reasons;

8) rehabilitation treatment and medical rehabilitation of tuberculosis patients and survivors of tuberculosis;

9) palliative care and nursing care for certain categories of the population;

10) postmortem diagnostics for:

pathological autopsy;

chronic diseases subject to dynamic observation, socially significant diseases;

infectious diseases and diseases that pose a danger to others;

11) preparation of a corpse for the removal of organs and (or) tissues, removal, conservation, procurement, storage, transportation of tissue (parts of tissue) and (or) organs (parts of organs) for the purpose of transplantation of tissues (parts of tissue) or organs (parts of organs).

4. Provision of medicines, medical devices, specialized medicinal products, immunobiological preparations within the guaranteed volume of free medical care shall be carried out:

1) in the provision of emergency, inpatient and inpatient care - in accordance with the medicinal forms of healthcare organizations;

2) in the provision of primary health care - in accordance with the list of medicines, medical devices, and specialized medical products approved by the authorized body for free and (or) preferential provision of certain categories of citizens with certain diseases (conditions).

5. When providing a guaranteed volume of free medical care, healthcare entities shall use medicines, medical devices, and specialized medical products registered in the Republic of Kazakhstan. Medicines shall be included in the Kazakhstan National Pharmaceutical Formulary.

It shall be allowed to use medicines and medical devices unregistered in the Republic of Kazakhstan for the provision of medical care according to the vital indications of a specific patient or for the provision of medical care to a limited contingent of patients with rare and (or) especially severe pathology in the manner determined by the authorized body.

6. The purchase of services from health care entities within the guaranteed volume of free medical care shall be carried out by the social health insurance fund.

7. The preferential right to conclude contracts within the guaranteed volume of free medical care shall be vested in accredited healthcare organizations, as well as entities in the field of circulation of medicines and medical devices that have received a certificate of compliance of the facility with the requirements:

- 1) good manufacturing practice (GMP) when purchasing medicines and concluding long-term contracts for the supply of medicines and medical devices;
- 2) good distribution practice (GDP) in the procurement of medicines, pharmaceutical services for the provision of a guaranteed volume of free medical care and the conclusion of long-term contracts for the storage and transportation of medicines and medical devices;
- 3) Good Pharmacy Practice (GPP) in the procurement of pharmaceutical services.

Footnote. Article 34 as amended by Law of the Republic of Kazakhstan No. 208-VI dated 28.12.2018 (shall be enforced since 01.01.2020).

Article 34-1. Principles for the formation of a guaranteed volume of free medical care

1. The guaranteed volume of free medical care shall be formed on the basis of the principles of universality, accessibility, evidence, realism, and controllability.
2. The principle of universality shall imply universal and equal coverage of the minimum amount of medical care, regardless of the level of income and social status of the persons specified in paragraph 1 of Article 34 of this Code.
3. The principle of accessibility shall consist in the possibility of receiving by the persons specified in paragraph 1 of Article 34 of this Code a guaranteed volume of free medical care in the territory of the Republic of Kazakhstan.
4. The principle of evidence shall imply the availability of proven scientific data on the effectiveness and safety of medical services and medicines included in the list of guaranteed volume of free medical care.
5. The principle of realism shall imply that the guaranteed volume of free medical care corresponds to the parameters of the state budget.
6. The principle of regulation shall consist in state regulation of tariffs for medical services and price caps for medicines provided in the provision of a guaranteed volume of free medical care.

Footnote. Chapter 9 is supplemented by Article 34-1 in accordance with the Law of the Republic of Kazakhstan dated 19. 05. 2015 No. 315-V (shall be enforced upon expiry of ten calendar days after its first official publication); as amended by Law of the Republic of Kazakhstan No. 208-VI dated December 28, 2018 (shall be enforced since January 1, 2020).

Article 34-2. Objectives of providing medical care within the guaranteed volume of free medical care

The objectives of providing medical care within the guaranteed volume of free medical care shall be:

- 1) diagnosis and treatment of diseases;
- 2) control over complications of chronic diseases, damage to organs and tissues;
- 3) prevention of disease progression in the early stages and their consequences;
- 4) medical care during pregnancy and childbirth;
- 5) the formation of the patient's skills to control their own health;
- 6) medical care for incurable patients in the terminal (end) stage of the disease.

Footnote. Chapter 9 as supplemented by Article 34-2 in accordance with Law of the Republic of Kazakhstan No. 208-VI dated December 28, 2018 (shall be enforced since January 1, 2020).

Article 34-3. Minimum social standards in health care

The guaranteed volume of free medical care, ensuring the availability of healthcare services to the population shall be the minimum social standards in the healthcare sector in accordance with the Law of the Republic of Kazakhstan "On Minimum Social Standards and Their Guarantees."

Footnote. Chapter 9 as supplemented by Article 34-3 in accordance with Law of the Republic of Kazakhstan No. 208-VI dated December 28, 2018 (shall be enforced since January 1, 2020).

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) treatment with medicines not included in the drug formulary of the healthcare organization;

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) providing medical assistance under a contract with the organization, including voluntary medical insurance;

8) provision of additional services;

9) providing medical assistance to foreigners and stateless persons, except for cases stipulated by paragraph 5 of Article 88 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 provision of paid services in healthcare organizations shall be determined by the authorized body.

Footnote. Article 35 as amended by the laws of the Republic of Kazakhstan dated 29.09.2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2016); dated 30.06.2017 No. 80-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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. Types of medical care

Types of medical care shall be:

- 1) first aid;
- 2) pre-doctor care;
- 3) qualified medical care;
- 4) specialized medical care;
- 5) high-tech medical service;
- 6) medical and social assistance.

Footnote. Article 38 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 38-1. First aid

1. First aid shall be a set of urgent basic measures to save a person's life and prevent complications in emergency conditions carried out at the scene of an accident by the victim himself (self-help) or by another person nearby (mutual aid).

2. Basic first aid measures shall be determined by health care standards.

Footnote. Chapter 10 shall be supplemented by Article 38-1 in accordance with the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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. is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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

Footnote. Article 39 as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 40. Adequate medical assistance

1. Qualified medical assistance shall be medical assistance provided by medical personnel with higher medical education in diseases, that do not require specialized methods of diagnosis, treatment and medical rehabilitation, including using telemedicine.

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); dated 06.04.2015 № 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 41. The specialized medical assistance

1. Specialized medical assistance shall be medical assistance, provided by profile specialists in diseases, requiring special methods of diagnosis, treatment and medical rehabilitation, including using telemedicine.

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 volume of the specialized medical care shall be established by the authorized body and local bodies of state management of health care of regions, cities of republican significance and the capital.

Footnote. Article 41 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 210-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 42. High-tech medical services

1. Coordination of activities of medical organizations, providing high-tech medical services shall be carried out by the authorized body.

2. The types and procedures for provision of high-tech medical services shall be determined by the authorized body.

Footnote. Article 42 as amended by the Law of the Republic of Kazakhstan dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2016).

Article 43. Medical and social assistance

1. Medical and social assistance shall be medical and socio-psychological assistance, provided to the citizens with socially significant diseases, the list of which shall be determined by the authorized body.

2. The procedure of medical and social assistance provided to citizens suffering from socially significant diseases shall be established by the authorized body.

Footnote. Article 43 is in the wording of the Law No. 239-V of the Republic of Kazakhstan dated 29. 09. 2014 (shall be enforced upon expiry of ten calendar days after its first official publication); as amended by the Law of the Republic of Kazakhstan dated 06. 04.

2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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) is excluded by the Law of the Republic of Kazakhstan dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2016);

8) is excluded by the Law of the Republic of Kazakhstan dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2016);

9) traditional medicine, alternative medicine (healing).

Footnote. Article 44 as amended by the Law of the Republic of Kazakhstan dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2016).

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) sanitary and anti-epidemic and sanitary-preventive measures in the foci 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;

5) explanatory work on prevention of socially significant diseases.

2. Primary health assistance shall be provided by the district therapists, pediatricians, general practitioners, paramedics, midwives, social workers in the field of healthcare and by nurses.

3. The activities of organizations, providing primary health assistance shall be built on a territorial principle in order to ensure the availability of medical care to the citizens at their place of residence and (or) attachment, taking into account the right to choose a medical organization.

4. Types and volume of primary health assistance shall be established by the Government of the Republic of Kazakhstan.

4-1. The procedure for provision of primary health care, as well as attachment to primary health care organizations, shall be determined by the authorized body.

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); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2016); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 46. Consultative and diagnostic assistance

1. Consultative and diagnostic assistance - specialized medical assistance, including the use of high-tech medical services without round-the-clock medical supervision.

2. The procedure for providing consultative and diagnostic assistance shall be established by the authorized body.

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); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2016).

Article 47. Inpatient care

1. Inpatient care shall be the form of providing pre-medical, qualified, specialized medical assistance, including using high-tech medical services, with round-the clock medical supervision.

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

3. The procedure for providing inpatient care shall be established by the authorized body.

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); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2016); dated 30.06.2017 No. 80-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 48. Hospital replacing assistance

1. Hospital replaced assistance is the form of pre-medical, qualified, specialized medical assistance, including with the use of high-tech medical services, with medical supervision.

2. The procedure for providing hospital-replaced assistance shall be established by the authorized body.

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); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2016); dated 30.06.2017 No. 80-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 49. Emergency medical assistance

1. Emergency medical assistance shall be a form of medical care in case of illnesses and conditions, requiring emergency medical care to prevent significant harm to health and /or eliminate the threat to life, as well as at the need to transport organs (parts of organs) for subsequent transplantation.

2. An emergency medical service shall be created in order to provide emergency medical care in the manner, established by the legislation of the Republic of Kazakhstan in the field of healthcare.

Footnote. Article 49 is in the wording of the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 50. Sanitary aviation

Sanitary aviation shall be a form of providing emergency medical care to the population when it is impossible to provide medical care due to the lack of medical equipment and (or) specialists of the relevant specialty and (or) qualification in a medical organization at the location of the patient. The medical care in the form of air ambulance shall be provided through delivering of the qualified specialists to the destination or transporting the patient (s), as well as organs (parts of organs) and (or) tissues (parts of tissues) for subsequent transplantation into the appropriate medical organization by air.

Footnote. Article 50 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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 procedure for restorative treatment and medical rehabilitation, including children's medical rehabilitation, shall be established by the authorized body.

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); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 53. Palliative care and nursing care

1. Palliative care shall be provided under the guidance of a doctor in specialized structural units (departments, rooms, beds, cabinets) of health care organizations, independent specialized medical organizations (hospices) or in the form of inpatient care at home.
2. Nursing care shall be provided in the cases that do not require medical supervision, in specialized structural units (departments, rooms, beds, cabinets) of health care organizations, independent specialized medical organizations (nursing care hospitals) or in the form of inpatient care at home.
3. The procedure for provision of palliative care and nursing care shall be determined by the authorized body.

Footnote. Article 53 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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 of ten 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. The regulation on the activities of organizations and (or) structural units of healthcare organizations, performing laboratory diagnostics, as well as the types of research conducted by them, shall be established by the authorized body.

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); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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 the spouse, close relatives or legal representative of the deceased, the pathoanatomical autopsy may be performed by an independent expert (experts) in the manner established by the authorized body.

3. The regulation on the activities of organizations and (or) structural units of healthcare organizations performing pathoanatomical diagnostics, as well as the procedure for performing pathoanatomical autopsy shall be established by the authorized body.

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); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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 medicines and medical devices;
- 7) scientific and medical expertise.
- 8) expertise of the connection of the disease with the performance of the employee's work (official) duties;
- 9) health care technology assessment.

3. Examination in the field of health care, except for the examination of medicines and medical devices during state registration, re-registration and introduction of changes to the registration dossier, shall be carried out by individuals and legal entities on the basis of an appropriate license and (or) legal entities - on the basis of an accreditation certificate.

Footnote. Article 57 as amended by the laws of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 29.03. 2016 No. 479-V (shall be enforced from 01.01.2017); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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. For conducting internal expertise in the medical organization, a patient support and internal control (audit) service shall be created. The structure and composition of this service shall be approved by the head of the organization, depending on the volume of provided medical services.

The patient support and internal control (audit) service shall conduct current analysis of organization of medical care, clinical activities of medical organization, detection of violations of the procedure for provision of medical assistance and standards, as well as consideration in a period not exceeding five calendar days, of appeals of patients being treated.

Based on the results of the audit, the internal control (audit) service shall make proposals on eliminating the identified causes and conditions for reducing the quality of provided medical services to the head of the medical organization.

For conducting an internal expertise of the quality of medical services, an internal expertise service for the quality of medical services, provided by its subordinate medical organizations shall be created by the Administration of the President of the Republic of Kazakhstan.

The structure and composition of this service shall be approved by the head of the Administration of the President of the Republic of Kazakhstan.

4. External expertise of the quality of medical services shall be conducted:

1) by the authorized body, as well as with the involvement of independent experts at commission analysis on cases, determined by the authorized body;

2) by independent experts when they are attracted by individuals or legal entities in cases of disagreement with the conclusion of internal and external expertise, as well as by healthcare subjects for conducting an independent expertise on a contractual basis.

5. The procedure for organizing and conducting internal and external expertise of the quality of medical services shall be established by the authorized body.

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); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 29. 03. 2016 No. 479-V (shall be enforced from 01.01.2017).

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 for the expertise of temporary incapacity for work, as well as the issuance of a sick leave and a certificate of temporary incapacity for work shall be established by the authorized body.

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); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 60. Military medical examination

1. Military medical expertise shall be conducted to confirm medical fitness for the military service in the Armed Forces, other troops and military units of the Republic of Kazakhstan or to the service in special state bodies, internal affairs bodies, criminal-executive system, firefighting service, anti-corruption service, bodies of the Prosecutor's Office, service of economic investigation of state revenue bodies (hereinafter - military service or service in special state bodies, law enforcement agencies (further - mutilation), as well as determining the causal connection of diseases, injuries (wounds, injuries, contusions) and death of citizens

in connection with the passage (performance of duties) of military service or service in special state and law enforcement agencies and military gathering.

For special state bodies, military medical expertise shall be carried out by the bodies of military medical expertise of national security agencies and the State security service of the Republic of Kazakhstan.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. Requirements for the conformity of health state for the service in the Armed Forces, other troops and military units of the Republic of Kazakhstan, special state bodies, internal affairs bodies and state aviation shall be approved by central executive bodies in the field of defense, internal affairs, national security agencies and the service of State protection of the Republic of Kazakhstan in agreement 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.); as amended by the Law of the Republic of Kazakhstan dated 07.11.2014 No. 248-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 10.01.2015 No. 275-V (shall be enforced upon expiry of ten 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. Sanitary-epidemiological expertise - a complex of organoleptic, sanitary-hygienic, epidemiological, microbiological, virological, parasitological, sanitary-chemical, biochemical, toxicological, radiological, radiometric, dosimetric measurements of physical factors, other studies and tests, as well as expertise of projects for the purposes of assessment of the conformity of projects, products, objects of entrepreneurial and (or) other activity with normative legal acts in the field of sanitary epidemiological welfare of population and hygienic standards.

2. Sanitary-epidemiological expertise shall be carried out by state bodies and organizations of sanitary-epidemiological service within the limits of competence by orders or instructions of officials of sanitary-epidemiological service, customs bodies and applications of individuals and legal entities in the manner determined by the state body in the field of sanitary and epidemiological welfare of population, with the exception of sanitary-epidemiological expertise of projects.

Sanitary and epidemiological expertise of construction projects for epidemically significant objects, as well as urban development projects shall be carried out by experts certified in the manner prescribed by the legislation of the Republic of Kazakhstan on architectural, urban development and construction activities.

3. Sanitary-epidemiological expertise of projects shall be carried out:

1) for the projects (feasibility studies and design estimates) intended for construction of epidemically significant objects by state or accredited expert organizations as part of a comprehensive non-departmental expertise;

2) for urban development projects, subject to approval by the Government of the Republic of Kazakhstan or maslikhats of oblasts, cities of republican significance and the capital.

3-1. For the projects, not provided by paragraph 3 of this Article, sanitary and epidemiological expertise shall be carried out by the state bodies of the sanitary and epidemiological service.

Sanitary-epidemiological expertise in the part of sanitary-epidemiological laboratory researches shall be carried out by state organizations of sanitary-epidemiological service.

4. Sanitary-epidemiological laboratory researches shall be the part of sanitary-epidemiological expertise, related to organoleptic, sanitary-hygienic, toxicological, sanitary-chemical, biochemical, microbiological, epidemiological, bacteriological, virological and parasitological laboratory reseraches, energy and biological value studies of food products , noise measurements, vibration, electromagnetic fields and physical factors, radiation studies, including radiometry and dosimetry.

The list and volumes (quantity) of sanitary-epidemiological laboratory studies shall be established by the state body in the field of sanitary and epidemiological welfare of population.

5. For the conduct of sanitary and epidemiological expertise upon applications of individuals and legal entities, financing and submission of the required documentation shall be provided by them.

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. Based on the inspection results and (or) preventive control, and (or) sanitary and epidemiological expertise, the state bodies of the sanitary and epidemiological service shall issue a sanitary and epidemiological opinion for:

1) operated objects of industrial and civil purpose;

2) is excluded by the Law of the Republic of Kazakhstan dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

3) drafts of normative documentation on maximum permissible emissions and maximum permissible discharges of harmful substances and physical factors into the environment, zones of sanitary protection and sanitary-defended zones, raw materials and products;

4) products, subject to state sanitary and epidemiological supervision, including the approval of shelf life and storage conditions for food products;

5) materials on chemical, biological, toxicological, radiological load on soil, water bodies and atmospheric air.

9. On the basis of sanitary-epidemiological expertise, a sanitary-epidemiological conclusion shall be issued.

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.); dated 16.05.2014 No. 203-V (shall be enforced upon expiry of six months after its first official publication); dated 07.11.2014 No. 248-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 29. 12. 2014 No. 269-V (shall be enforced from 01.01.2015); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 27.02.2017 No. 49-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 24.05.2018 No. 156-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 62-1. Sanitary and epidemiological audit

1. Sanitary-epidemiological audit shall be conducted by the auditor.

2. Sanitary-epidemiological audit shall be conducted on the basis of the requests of the objects owners, subject to state sanitary and epidemiological supervision (hereinafter- the "applicant"), taking into account specific tasks, terms and volumes of sanitary and epidemiological audit envisaged by the contract for conducting sanitary and epidemiological audit between the applicant and the auditor, which shall be concluded in accordance with the Civil Code of the Republic of Kazakhstan.

3. The results of the sanitary and epidemiological audit shall be reflected in the audit report with conclusions about the compliance or non-compliance of the object.

The basis for the exemption of objects of high epidemiological significance from inspections, conducted in a special manner, shall be the receipt by the official of the sanitary and epidemiological service of an audit report with conclusions about the compliance of the object with the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of the population and hygienic standards.

Terms of exemption from inspections shall be established by the criteria for assessing the degree of risk, determined by the authorized body and the authorized body on entrepreneurship.

4. For conducting sanitary-epidemiological audit, individuals and legal entities must meet the following qualification requirements:

1) for individuals:

the presence of higher medical education of sanitary and epidemiological profile;

the presence of the highest qualification category of a sanitary-hygienic doctor in the relevant specialty or specialty of the general hygiene doctor or the presence of the highest qualification category of the epidemiologist or the highest qualification category of the public health physician (epidemiologist);

2) for legal entities, the presence of qualified personnel, meeting the requirements, established by subparagraph 1) of this paragraph in the staff.

5. Individuals and legal entities shall be obliged to inform the state body in the sphere of sanitary and epidemiological welfare of population before the beginning of the activity on conducting sanitary and epidemiological audit in the order established by the Law of the Republic of Kazakhstan "On Permits and Notifications".

6. The procedure for sanitary-epidemiological audit shall be carried out in several stages and shall include:

1) registration of an application for a sanitary and epidemiological audit;

2) preliminary analysis of the documents submitted by an applicant;

3) conclusion of a contract for the conduct of sanitary and epidemiological audit;

4) establishment of the objectives of sanitary and epidemiological audit;

5) drawing up a plan for conducting sanitary and epidemiological audit;

6) conducting of sanitary and epidemiological audit (inspection of the object, analytical processing of materials, conducting comparative analysis and assessment of the degree of sanitary and epidemiological danger of planned or ongoing activities, sufficiency and reliability of justifications for the realization of an object);

7) compilation and submission of an audit report to the applicant.

7. For conducting of sanitary-epidemiological audit, financing shall be provided and the required documentation shall be submitted in the manner established by paragraph 8 of this Article by the applicant.

8. For conducting of sanitary-epidemiological audit of the object, the applicant shall submit the following documents to the auditor:

1) an application for conducting of sanitary-epidemiological audit;

2) materials, relating to the object, subject to sanitary and epidemiological audit (acts of examinations of the bodies of state sanitary and epidemiological service for the last year (in the absence of the latter), approved by the head of the state body in the field of sanitary and epidemiological welfare of the population, the form of determining the degree of risk of an epidemic-significant object, sanitary and epidemiological conclusion on the compliance of the object with the requirements of sanitary regulations);

3) in the presence, documentation on the management system of the economic subject and previous conclusions on sanitary-epidemiological audit;

4) other materials, necessary for the assessment of the object.

9. Auditors included in the state electronic register of permits and notifications must annually, by the tenth of January after the reporting year, submit to the state body in the field of sanitary and epidemiological welfare of the population the information on the conducted sanitary and epidemiological audit in a form, approved by the state body in the field of sanitary and epidemiological welfare of the population.

10. Based on the results of sanitary and epidemiological audit carried out in accordance with the plan, an audit report shall be prepared on the compliance (non-compliance) of the object with sanitary rules in accordance with the form, established by the procedure for conducting sanitary epidemiological audit.

11. The procedure for conducting a sanitary and epidemiological audit shall be determined by the state body in the field of sanitary and epidemiological welfare of the population.

12. The results of sanitary-epidemiological audit shall be recognized as invalid in cases when in preparation of the audit report the following cases were admitted:

1) violation of the procedure for conducting sanitary and epidemiological audit;

2) non-fulfillment or distortion of the requirements of the legislation of the Republic of Kazakhstan, sanitary rules and hygienic standards;

3) violations of the rights of citizens to a favorable environment for life and health, other sanitary and epidemiological rights and interests of population, the rights of the participants in sanitary and epidemiological process;

4) other violations of the rights of parties, involved in sanitary-epidemiological audit.

13. Auditors, carrying out sanitary epidemiological audit shall:

1) provide comprehensive, objective, high-quality audit;

2) comply with the requirements of the legislation of the Republic of Kazakhstan in the field of sanitary and epidemiological welfare of population and other regulatory legal acts;

3) conduct sanitary-epidemiological audit on the basis of documents of state sanitary-epidemiological regulation, normative technical documents;

4) observe the established deadlines and the procedure for conducting sanitary and epidemiological audit, provided by the terms of the contract.

Footnote. Chapter 12 is supplemented by Article 62-1 in accordance with the Law of the Republic of Kazakhstan dated 29.12.2014 No. 269-V (shall be enforced from 01.01.2015); as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 62-2. Restriction of the right for conducting sanitary and epidemiological audit

It is prohibited to conduct sanitary-epidemiological audit by the auditor, the executors of which are:

1) the participant, creditor of the audited subject;

2) in labor contract or close relatives or possessors of the officials of the subject being audited, as well as of a shareholder (participant), owning ten or more percent of shares (stakes in the charter capital) of the subject being audited;

3) have personal property interests in the subject being audited;

4) have monetary obligations to the audited subject or such obligations are available to the audited subject before them, with the exception of the obligations to conduct sanitary and epidemiological audit.

Footnote. Chapter 12 is supplemented by Article 62-2 in accordance with the Law of the Republic of Kazakhstan dated 29.10.2015 No. 376-V (shall be enforced from 01.01.2016).

Article 63. Examination of medicines and medical devices

Footnote. The title of Article 63 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

1. Examination of medicines and medical devices shall be a comprehensive assessment of safety, quality and effectiveness, the "benefit-risk" ratio of medicines and medical devices in the pre-registration and post-registration periods, carried out on the basis of materials for the conduct of clinical studies, materials of registration dossier, laboratory tests on compliance with the regulated quality, pharmacovigilance data, monitoring of the safety, quality and effectiveness of medical devices in the order, determined by the authorized body.

2. Examination of medicines and medical devices shall belong to the state monopoly and shall be carried out by the state expert organization in the field of circulation of medicines and medical devices.

Prices for goods (works, services), produced and (or) realized by a state monopoly subject shall be established by the authorized body in agreement with the antimonopoly body.

3. Requirements for the safety, quality and effectiveness of pharmaceutical substances (active pharmaceutical substances), medicinal raw materials, medicinal plant materials, bulk products of medicines or medical devices, original medicines, biotechnological medicinal products, immunological medicinal products (immuno-biological medicinal products), reproduced medicines (generics), homeopathic medicines, bio-analogical medical products (bio-analogues, biosimilar medicines, bio-similars) and medical devices shall be imposed during the examination of medicines and medical devices in the manner, determined by the authorized body.

4. The grounds for the negative opinion of the examination of medicines and medical devices shall be:

1) failure to submit the complete set of the registration dossier after the issuance of comments to an applicant in the process of conducting the expertise within the time limits, established by the procedure determined by the authorized body;

2) submission of inaccurate information by an applicant;

- 3) the ratio of the expected benefits to the possible risks, associated with the use of the medicine, is not favorable;
 - 4) lower quality and safety indicators, regulated by the State Pharmacopoeia of the Republic of Kazakhstan or pharmacopoeias recognized as operating on the territory of the Republic of Kazakhstan, or in comparison with previously registered analogues;
 - 5) the presence of substances and materials in the composition of a medicine prohibited for the use in the Republic of Kazakhstan;
 - 5-1) the presence of solid dosage forms of preservatives in the composition;
 - 6) obtaining of negative results from one of the stages of examination and (or) negative opinions of experts of relevant organizations;
 - 7) discrepancy between actual production conditions and the quality assurance system for the conditions, ensuring the declared safety, efficiency and quality based on the results of the production assessment and the quality assurance system;
 - 8) an applicant's refusal to organize a visit to the enterprise (production site) in order to assess the production conditions and the quality assurance system, in accordance with the requirements of the legislation of the Republic of Kazakhstan;
 - 9) identification of irrational combinations of medicines;
 - 10) an applicant has not proven the clinical efficacy and safety of the medicine;
 - 11) the quality of the medicine is not confirmed;
 - 12) a proven unfavorable "benefit - risk" ratio or an identified lack of therapeutic efficacy, provided that the conditions of use of the medicine, described in the approved general characteristic of the medicine during the post-registration period are met;
 - 13) facts, established according to the data of pharmacovigilance, indicating an unfavorable "benefit - risk" ratio, including a significant increase in the frequency of reporting of unwanted reactions compared with the data, specified in the approved general characteristic of the medicine;
 - 14) discrepancy between the qualitative and quantitative composition of the drug with the declared one or a repeated non-compliance of the quality of the medicinal product during its circulation in the market with the declared one at the time of its registration;
 - 15) the failure of the holder of the registration certificate to fulfill the pharmacovigilance obligations or obligations under the registration procedure;
 - 16) the changes made have a negative effect on the benefit-risk ratio of the medicine.
- 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); dated 29 . 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).**

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

1. Evaluation of the safety and quality of medicines and medical devices registered in the Republic of Kazakhstan shall be carried out by determining the compliance of the safety and quality of medicines and medical devices with the data of the registration dossier, quality regulatory documents on the basis of which they were registered in the Republic of Kazakhstan.

2. Evaluation of the safety and quality of medicines and medical devices registered in the Republic of Kazakhstan shall belong to the state monopoly and shall be carried out by the state expert organization in the field of circulation of medicines and medical products.

Prices for goods (works, services) produced and (or) sold by a subject of state monopoly shall be established by the authorized body in coordination with the antimonopoly authority.

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); is in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 64. Scientific and medical expert examination

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

1) projects of applied research programs;

2) is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

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.

Footnote. Article 64 as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 64-1. Health technology assessment

1. The objects of health technology assessment shall be the health technologies that are proposed for inclusion (exclusion) in the lists (from the lists) of reimbursement within the guaranteed volume of free medical care and in the system of compulsory social health insurance.

2. The procedure for assessing the health technology shall be determined by the authorized body.

Footnote. Chapter 12 shall be supplemented with Article 64-1 in accordance with the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

SECTION 4. Pharmaceutical activities and circulation of medicines and medical devices

Footnote. The title of section 4 as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Chapter 13. PHARMACEUTICAL ACTIVITY

Article 65. System of circulation of medicines and medical devices

The unified system of circulation of medicines and medical products shall include:

- 1) the state body in the field of circulation of medicines and medical devices and its territorial sub-divisions;
- 2) the state expert organization in the field of circulation of medicines and medical devices and its territorial sub-divisions.

Footnote. Article 65 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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 activities shall include the following types:

- 1) the production of medicines;
- 2) the production of medical devices;
- 3) the manufacture of medical products;
- 4) the manufacture of medical devices;
- 5) wholesale sales of medicines;
- 6) wholesale sales of medical products;
- 7) retail sales of medicines;
- 8) retail sales of medical products.

Footnote. Article 66 as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 66-1. State Pharmacopoeia of the Republic of Kazakhstan

1. The quality and safety of medicines and medical devices on the pharmaceutical market of the Republic of Kazakhstan shall be established by the requirements of the State Pharmacopoeia of the Republic of Kazakhstan.

2. The State Pharmacopoeia of the Republic of Kazakhstan shall be harmonized with the requirements of the leading pharmacopoeias of the world and shall be subject to periodic updates due to changes in their standards and peculiarities of the development of the pharmaceutical market of the Republic of Kazakhstan.

3. In the absence of the relevant articles (monographs) in the State Pharmacopoeia of the Republic of Kazakhstan, current publications of the leading pharmacopoeias of the world recognized by the authorized body shall be used.

4. General articles of the State Pharmacopoeia of the Republic of Kazakhstan shall define general requirements for:

- 1) the quality of pharmaceutical substances (active pharmaceutical substances), medicines ;
- 2) reagents, standard samples, methods and test methods used to control their quality;
- 3) packaging materials and containers.

5. Private articles of the State Pharmacopoeia of the Republic of Kazakhstan shall define specific requirements for the quality of pharmaceutical substances (active pharmaceutical substances), medicines.

6. The State Pharmacopoeia of the Republic of Kazakhstan shall be a mandatory requirement for individuals and legal entities, engaged in production, manufacture, sale, storage, quality control, examination of medicines and medical products during state registration, re-registration and introduction of changes to the registration dossier.

7. The State Pharmacopoeia of the Republic of Kazakhstan shall be developed by the state expert organization in the field of circulation of medicines and medical devices.

The procedure for development, execution, coordination, approval and introduction of amendments and additions to the State Pharmacopoeia of the Republic of Kazakhstan shall be determined by the authorized body.

8. The State Pharmacopoeia of the Republic of Kazakhstan on the structure, design of monographs, numbering of sections and pharmacopoeial articles (monographs), symbols, image formulas must comply with the leading pharmacopoeias of the world, recognized by the authorized body.

Footnote. Chapter 13 is supplemented with Article 66-1 in accordance with the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); is in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 67. Production of medicines and medical devices

1. The production of medicines and medical devices shall be a pharmaceutical activity, including the totality of all the work necessary for the serial production of medicines and medical products, related to the acquisition of raw materials, materials, semi-finished products, equipment, components and technological process, including the implementation of one of its stages, storage, sale of products, as well as all types of accompanying control.

2. Production of medicines in the territory of the Republic of Kazakhstan shall be carried out by the subjects in the field of circulation of medicines and medical devices in accordance with the good manufacturing practice (GMP) of the Republic of Kazakhstan and (or) the Eurasian Economic Union and on the basis of a license, obtained in the manner, established by the legislation of the Republic of Kazakhstan.

Note of RCLI!

Sub-paragraph 2 of paragraph 2 shall be enforced for organizations for production of medicines, pharmacy warehouses from 01.01.2021 in accordance with the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI.

Subjects in the field of circulation of medicines and medical devices in the manufacture of medicines must comply with the requirements of the good manufacturing practice (GMP).

3. Stability studies, determination of the shelf life and re-control of medicines shall be carried out by the manufacturer of the medicinal product in accordance with the rules, approved by the authorized body.

Stability studies, establishment of the shelf life of medical devices shall be conducted by the manufacturer of medical devices in accordance with international standards.

4. It shall be prohibited to manufacture medicines and medical devices:

1) that have not passed the state registration in the Republic of Kazakhstan, except for the medicines and medical devices, intended for examination during their state registration, debugging and launching of equipment and technological processes, preclinical (non-clinical) and clinical studies, contract manufacturing and production of medicines and medical products for export;

2) without a license for the right to manufacture medicines and medical devices;

3) with violation of good manufacturing practices and rules for production of medical devices.

5. The manufactured and imported medicines:

1) should not contain dyes and auxiliary substances prohibited for use in the Republic of Kazakhstan, the list of which is approved by the authorized body;

2) should be subject to control in accordance with the regulatory document on the quality of medicines, developed by the manufacturer of medicines and agreed by the state expert organization during the examination in accordance with the rules, approved by the authorized body;

3) must be made of a pharmaceutical substance (active pharmaceutical substance), produced in the conditions that are not lower than the requirements of the good manufacturing

practice (GMP) of the Republic of Kazakhstan and (or) the Eurasian Economic Union and declared during the state registration, re-registration and changes of the registration dossier of the medicine.

Medicines, produced in the Republic of Kazakhstan for export only shall not be subject to the state registration and sale in the Republic of Kazakhstan.

6. The manufactured and imported medical devices should be subject to control in accordance with the regulatory document of the medical device, submitted by the manufacturer of the medical device during the examination of the medical device for the purposes of the state registration, re-registration and changes in the registration dossier of the medical device.

Medical products, manufactured in the Republic of Kazakhstan for export only shall not be subject to the state registration and sale in the Republic of Kazakhstan.

7. Production and sale of patented medicines and medical devices shall be carried out in accordance with the legislation of the Republic of Kazakhstan.

8. Production of medical devices, intended for diagnosis or treatment, should ensure their safety, provide for their use in accordance with the functional purpose and eliminate the risk of user error in interpreting the results of diagnosis or treatment.

9. The manufacturer of medicinal products shall ensure that at least one authorized person of the manufacturer shall be in the staff, responsible for fulfilling the duties in accordance with the requirements of the good manufacturing practice (GMP) of the Republic of Kazakhstan and (or) the Eurasian Economic Union.

Footnote. Article 67 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 68. Manufacture of medicines and medical devices

The manufacture of medicines and medical devices shall be carried out by subjects in the field of circulation of medicines and medical devices that are licensed to manufacture medicines and medical devices in accordance with the rules, approved by the authorized body. Manufactured medicines shall be subject to intra-pharmacy control in the manner, determined by the authorized body.

Footnote. Article 68 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 69. Wholesale and retail sales of medicines and medical devices

Footnote. The title of Article 69 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

1. The wholesale sale of medicines and medical devices shall be carried out by subjects in the field of circulation of medicines and medical devices who have received the appropriate

license for wholesale distribution in pharmacy warehouses or have notified of the commencement of activities through the medical device warehouse in the manner, prescribed by the Law of the Republic of Kazakhstan "On Permits and Notifications".

2. The retail sale of medicines and medical devices shall be carried out by subjects in the field of circulation of medicines and medical devices who have received a corresponding license for retail sales in pharmacies, pharmacy points, mobile pharmacies, or have notified of the commencement of activities through optics stores and medical devices stores in the manner, established by the Law of the Republic of Kazakhstan "On Permits and Notifications".

Note of RCLI!

Sub-paragraph 1 of paragraph 3 shall be enforced for pharmacies from 01.01.2023 in accordance with the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI.

3. Subjects in the field of the circulation of medicines and medical devices engaged in the retail sale of medicines must comply with the requirements of the good pharmacy practice (GPP).

Note of RCLI!

Sub-paragraph 2 of paragraph 3 shall be enforced for organizations for the production of medicines, pharmacy warehouses from 01.01.2021 in accordance with the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI.

Subjects in the field of the circulation of medicines and medical devices that carry out the wholesale distribution of medicines shall be obliged to comply with the requirements of the good distribution practice (GDP).

Subjects in the field of circulation of medicines and medical devices licensed or notifying of the commencement of activities in the manner, prescribed by the Law of the Republic of Kazakhstan "On Permits and Notifications" shall be allowed to engage in wholesale and retail sales of goods not related to medicines and medical products in accordance with the list, approved by the authorized body.

4. The wholesale and retail sale of medicines and medical products shall be prohibited:

- 1) if they have not passed the state registration in the Republic of Kazakhstan;
- 2) their quality is not confirmed by the conclusion on safety and quality in the manner, established by the legislation of the Republic of Kazakhstan in the field of health care;
- 3) if they do not meet the requirements of the legislation of the Republic of Kazakhstan in the field of health care;
- 4) if they are expired;

Note of RCLI!

Subparagraph 5) shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced from 01.01.2023).

Note of RCLI!

This version of subparagraph 5) shall be valid until 01.01.2023 in accordance with the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI.

5) medical specialists in health care organizations, except for the cases, specified in paragraph 6 of this article;

6) through warehouses for the temporary storage of medicines and medical devices.

5. Non-prescription sale of medicines, intended for the sale with the prescription of a doctor shall be forbidden.

The rules for assigning medicines to a prescription sale, rules for prescribing, recording and storing prescriptions shall be approved by the authorized body.

Note of RCLI!

Paragraph 6 shall be excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced from 01.01.2023).

Note of RCLI!

This version of paragraph 6 shall be valid until January 1, 2023 in accordance with the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI.

6. In remote settlements from the regional center, where there are no pharmacies, the sale of medicines and medical products may be carried out by individuals and legal entities through pharmacies in healthcare organizations, providing primary health care, counseling and diagnostic assistance, and through mobile pharmacies.

In the absence of pharmacy points, retail trade of medicines and medical products can be carried out through healthcare organizations, providing primary health care, counseling and diagnostic assistance.

In the absence of specialists with pharmaceutical education, specialists with medical education, who have been trained for their realization, shall be allowed to carry out retail trade of medicines and medical products.

7. Medicines and medical devices, imported and produced in the territory of the Republic of Kazakhstan before the expiration of the registration certificate deadline shall be used, circulated and operated in the territory of the Republic of Kazakhstan without restrictions.

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.); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (for the procedure of enactment see Art. 2); dated 29. 03. 2016 No. 479-V (shall be enforced from 01.01.2017); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Chapter 14. Circulation of medicines and medical devices

Footnote. The title of chapter 14 as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 70. Development of medicines and medical devices

1. Development of medicines shall include the search for and (or) creation of new active substances or their new combinations, the subsequent study of pharmacological properties, pharmaceutical development, preclinical (non-clinical) and clinical studies, as well as the development of technologies for the industrial production of medicines.

2. Development of medicines shall be carried out in compliance with the requirements of the good pharmaceutical practices to ensure their safety and efficacy.

3. Development of medical devices shall include the search for and (or) creation of a technical solution, invention, design, construction and testing of prototypes, as well as the development of technologies for the industrial production of medical products.

4. Development of medical devices shall be carried out in compliance with the requirements of international standards that ensure their safety and efficacy.

5. The rights of the developer of the medicinal product and the medical device shall be protected by the legislation of the Republic of Kazakhstan.

Footnote. Article 70 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 71. State registration, re-registration and introduction of changes to the registration dossier of a medicinal product or medical device

Footnote. The title of Article 71 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

1. The state registration of a medicinal product or a medical device shall be the procedure for determining the legality of the presence on the pharmaceutical market, assessing the safety, quality and efficacy of a medicinal product or medical device and putting a medicinal product or medical product for a specified period in the State Register of medicinal products and medical devices in the manner, determined by the authorized body.

2. The state re-registration of a medicinal product or a medical device shall be the procedure for extending the state registration of a medicinal product or a medical device, the state registration of which has expired, with the issuance of an unlimited registration certificate under the previous registration number and making an appropriate entry in the State Register of medicinal products and medical devices, carried out in the manner, determined by the authorized body.

3. Amendments to the registration dossier of a medicinal product or a medical device shall be carried out on the basis of an examination of changes made to the registration dossier

during the validity period of the registration certificate, in the manner, determined by the authorized body.

4. The following, produced in the Republic of Kazakhstan, as well as the medicines and medical devices, imported into its territory shall be subject to the state registration and re-registration:

1) medicines under the trade names, indicating the dosage form, dosage, packaging from each production site;

2) parapharmaceuticals;

3) medical products under the trade names from each production site;

4) consumables for medical devices, except those specifically designed by the manufacturer of the medical device for the use with medical devices, able to operate only with these consumables;

5) medical devices that are part of a specialized vehicle for provision of medical care;

6) bulk products of medicines or medical devices.

5. Trade name of a drug - the name under which the drug shall be registered.

6. Is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

7. Is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

8. Medicines and medical products, intended for circulation on the market of the Eurasian Economic Union shall be subject to registration according to the uniform rules in accordance with the regulatory legal acts of the Eurasian Economic Union.

8-1. A certificate shall be issued by the authorized body for a pharmaceutical product (CPP) for registration of domestic medicines abroad, in accordance with the rules approved by the authorized body.

8-2. Medicinal products, manufactured outside the Republic of Kazakhstan in the conditions not lower than the requirements of the good manufacturing practice (GMP) of the Republic of Kazakhstan shall be subject to the state registration, re-registration and introduction of changes to the registration dossier.

9. By the decision of an authorized body, a medicinal product or a medical device may be registered under the procedure of an accelerated examination.

The procedure for an accelerated examination of a medicinal product or a medical device shall be determined by the authorized body.

10. Is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

11. An obligatory condition for the state registration, re-registration and introduction of changes to the registration dossier of a medicinal product or a medical device shall be the examination of a medicinal product or a medical device.

Evaluation of the conditions of production and the quality assurance system shall be carried out by visiting the organization of the manufacturer of the medicinal product or a medical device at the expense of the applicant during the state registration of the medicinal product or medical device in the manner, determined by the authorized body.

Expenses related to the examination of a medicinal product and a medical device during their state registration, re-registration and introduction of changes in the registration dossier shall be covered by the applicants.

The expert organization shall be provided with a registration dossier, containing documents, the list of which is determined by the authorized body, as well as the samples of a medicinal product or a medical device, standard samples of pharmaceutical substances (active pharmaceutical substances) and their impurities, in the quantities sufficient for triple analysis, specific reagents and consumable materials, in the exceptional cases and on condition of return.

12. The following shall not be subject to the state registration:

1) medicines, manufactured in pharmacies;

2) pharmaceutical substances (active pharmaceutical substances), produced in the conditions of the good manufacturing practices;

3) pharmacopoeial medicinal plant raw materials;

4) medical products, manufactured for individual orders of patients solely for personal use, which are subject to special requirements in accordance with the prescription, issued by a medical specialist;

5) medicines and medical devices, manufactured in the Republic of Kazakhstan for export only;

6) exhibition samples of medicines and medical devices for exhibitions without the right for their further sale;

7) samples of medicines and medical devices that are received for preclinical (non-clinical) and clinical research and (or) testing;

8) laboratory instruments that are not used for the diagnosis of diseases;

9) components that are part of medical devices and are not used as a separate product or device;

10) radiopharmaceutical medicines, manufactured directly in health care organizations at the place of their use;

11) samples of medicines and medical devices for examination during the state registration.

13. Application for a state registration, re-registration and introduction of changes to the registration dossier of a medicinal product or a medical device shall be submitted by the developer or manufacturer of the medicinal product or medical device, or their authorized person.

Accounting and systematization of documents, submitted by the applicant during the state registration, re-registration and introduction of changes to the registration dossier of a medicinal product or a medical device shall be carried out in the manner, determined by the authorized body.

The state registration, re-registration and introduction of changes to the registration dossier of a medicinal product or a medical device shall be carried out by the state body in the field of circulation of medicinal products and medical devices on the basis of an application and a positive opinion of an expert organization on the safety, quality and efficacy of a medicinal product or medical device, issued following the results of the examination.

14. A fee shall be charged for the state registration, re-registration and issuance of a duplicate of the registration certificate of a medicinal product or a medical device in accordance with the Code of the Republic of Kazakhstan "On taxes and other obligatory payments to the budget" (Tax Code).

15. In the cases of a negative opinion on the results of the examination of the state expert organization in the field of circulation of medicinal products and medical devices and a failure to submit a full package of documents, established in the manner, determined by the authorized body, the applicant shall be rejected to make the state registration, re-registration and introduction of changes to the registration dossier of a medicinal product or a medical device.

16. According to the results of the state registration and re-registration of a medicinal product or a medical device, a registration certificate shall be issued in the form, established by the authorized body.

17. The decision on the state registration of a medicinal product or a medical device may be withdrawn in the manner, determined by the authorized body.

18. During the validity period of the registration certificate, the holder of the registration certificate of the medicinal product and the manufacturer of the medical product shall be responsible for the safety, quality and efficacy of the medicinal products or medical devices, registered in the market of the Republic of Kazakhstan, which must comply with the registration dossier, submitted for examination for the purposes of the state registration, re-registration and introduction of changes to the registration dossier of medical product or medical device.

19. The state expert organization in the field of circulation of medicines and medical devices and the state body in the field of circulation of medicines and medical devices shall not allow, without the consent of the applicant, disclosure and use for commercial purposes of the confidential information, provided for the state registration of the medicinal product,, contained in the application for the state registration, materials of examination of the medicinal product, as well as the registration dossier of medicinal product, containing new chemical substances, during six years from the date of the state registration of the medicinal product.

20. The provisions, envisaged in paragraph 19 of this Article, that do not allow the disclosure and use of confidential information for commercial purposes shall not apply to:

- 1) individuals or legal entities, that have been issued a compulsory license for using the medicine in accordance with the Patent Law of the Republic of Kazakhstan;
- 2) usage, production, import, export or distribution of a medicine for non-commercial purposes.

21. On the basis of a court decision, the disclosure and use of the information, specified in paragraph 19 of this Article shall be allowed without the consent of an applicant, in the presence of one of the following cases:

- 1) if the supply of medicines is insufficient to meet the needs of the population within twelve months from the date of registration in the Republic of Kazakhstan;
- 2) the need to protect public health in emergency situations or to ensure national security;
- 3) identification of actions, violating the requirements of the legislation of the Republic of Kazakhstan in the field of competition protection.

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); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 27.10.2015 No. 365-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 72. Pre-clinical (non-clinical) research of medicinal products and research (testing) of evaluation of biological effect of medical devices

1. The purpose of pre-clinical (non-clinical) research of medicinal products shall be to obtain the proofs of their pharmacological activity and safety through scientific methods.

Research (testing) of evaluation of the biological effects of medical devices shall be carried out to determine the acceptability of any potential adverse biological response, resulting from the contact of the medical device materials with the human body.

2. The procedure for the conduct of preclinical (non-clinical) studies and the requirements for the pre-clinical bases shall be determined by the authorized body.

Pre-clinical (non-clinical) studies shall be carried out in accordance with the good laboratory practice (GLP) of the Republic of Kazakhstan and (or) the Eurasian Economic Union.

The assessment of materials and the compliance of the conditions for the conduct of pre-clinical (non-clinical) research with the requirements of the good laboratory practice (GLP) of the Republic of Kazakhstan and (or) the Eurasian Economic Union shall be carried out within the framework of the pharmaceutical inspection in the manner, determined by the authorized body.

Footnote. Article 72 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 73. Technical testing of medical devices

1. Technical testing of medical devices shall be carried out in the form of tests and (or) evaluation and analysis of the data to verify the quality and safety when using them in accordance with the purpose, stipulated by the documentation of the manufacturer of the medical device.

2. Technical testing of medical devices shall be carried out in organizations, accredited to conduct technical tests in the manner, specified by the legislation of the Republic of Kazakhstan on accreditation in the field of conformity assessment.

3. The procedure for the conduct of technical testing shall be determined by the authorized body.

Footnote. Article 73 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 74. Clinical studies of medicinal products, medical devices, and clinical and laboratory tests of medical devices for in vitro diagnostics

1. Clinical studies of medicines and medical devices shall be carried out with the participation of a person as a subject to identify or confirm the clinical and (or) pharmacodynamic effects of a pharmacological or medicinal product under investigation and (or) to reveal unwanted reactions and (or) to study absorption, distribution, biotransformation and removal of medicines, assessment of safety and (or) functional characteristics of medical devices and (or) adverse events (incidents) of a medicinal product to establish safety and efficacy.

Clinical and laboratory tests of medical devices for in vitro diagnostics shall be carried out on analytical characteristics, clinical efficacy (if applicable) to establish the conformity of the medical device for in vitro diagnostics.

2. Clinical studies shall be carried out in accordance with the rules of the good clinical practice (GCP) of the Republic of Kazakhstan and (or) the Eurasian Economic Union.

3. The procedure for the conduct of clinical tests, clinical and laboratory testing of medical devices for in vitro diagnostics and the requirements for clinical bases shall be determined by the authorized body.

Footnote. Article 74 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 75. Labeling of medicines and medical devices

1. Medicinal products should enter the circulation with labels, applied on consumer packaging (primary and secondary), in a well-read typeface in the Kazakh and Russian languages, with instructions for medical use (package leaflet).

2. For medical workers on the Internet resources of the authorized body and the state expert organization in the field of circulation of medicines and medical devices the general characteristics of the medicine, approved by the authorized body during the state registration, shall be placed.

3. Medical devices must be delivered with the label, applied directly to the medical devices and (or) on consumer packaging, medical application instructions or operating manuals for a medical device.

4. Stickers may be used when importing a limited number of expensive orphan (rare) medicines.

The application of stickers on consumer packaging shall be carried out in the manner, determined by the authorized body.

5. The rules for labeling the medicines and medical devices shall be approved by the authorized body.

The procedure for the preparation and execution of instructions for medical use and the general characteristics of medicines and medical devices shall be determined by the authorized body.

Footnote. Article 75 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 75-1. Pharmaceutical inspectorate for good pharmaceutical practices

1. The Pharmaceutical inspectorate for good pharmaceutical practices shall be a structural subdivision of the state body in the field of circulation of medicines and medical devices and its territorial subdivisions, conducting a pharmaceutical inspection.

2. The state body in the field of circulation of medicines and medical devices shall coordinate the activities of the pharmaceutical inspectorate for the good pharmaceutical practices.

The state body in the field of circulation of medicines and medical devices and its territorial subdivisions shall issue or revoke certificates (opinions) for compliance with the requirements of the good pharmaceutical practices.

3. Pharmaceutical inspection shall be carried out in the following cases:

1) on the basis of the application of the subject in the field of circulation of medicines and medical devices to receive a certificate (opinion) or the extension of its effect, as well as in accordance with the good pharmacovigilance practice (GVP);

2) on the basis of the application of the subject in the field of circulation of medicines and medical devices, as well as for the purposes of licensing, registration, examination or

conducting investigations, related to the safety, quality and efficacy of medicines, medical devices, in accordance with the program of the pharmaceutical inspection;

3) based on the results of a previously conducted pharmaceutical inspection in order to confirm the elimination of the revealed nonconformities.

4. Validity period of the certificate of compliance of the object with the requirements of: the good manufacturing practice (GMP) is three years;

the good distribution practice (GDP); the good laboratory practice (GLP) - five years;

the good pharmacy practice (GPP) - the first two times for five years, with subsequent confirmation - indefinitely.

5. Pharmacies shall be subject to pharmaceutical inspections for compliance with the requirements of the good pharmacy practice (GPP), pharmacy (distribution) warehouses - for compliance with the requirements of the good distribution practice (GDP), organizations for production of medicines - for compliance with the requirements of the good manufacturing practice (GMP), organizations conducting preclinical (non-clinical) studies - for compliance with the requirements of the good laboratory practice (GLP), health care organizations carrying out clinical research - for compliance with the good clinical practice (GCP), holders of registration certificates of medicines - for compliance with the good pharmacovigilance practices (GVP).

6. Pharmaceutical inspections shall be carried out in the manner determined by the authorized body.

Footnote. Chapter 14 shall be supplemented with Article 75-1 in accordance with the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 76. Purchase of medicines and medical devices intended for the provision of minimum , basic and additional volumes of medical care, and medical care in the system of compulsory social health insurance

Footnote. The title as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication); No. 208-VI dated 28.12.2018 (shall be enforced since 01.01.2020).

1. Medicines intended for the provision of minimum, basic and additional volumes of medical care, and medical care in the system of compulsory social health insurance, shall be purchased under international non-proprietary names, and in case of individual intolerance to the patient - under trade names based on the conclusion of the medical advisory commission and decisions of the local representative body of the region, the city/town of republican status and the capital within the framework of the Kazakhstan national form. In the case of purchasing a multicomponent medicinal product, its composition shall be indicated.

2. In order to optimally and efficiently use budget funds, allocated for the procurement of medicines and medical devices within the guaranteed volume of free medical care, and the money of the compulsory social medical insurance, the medicines and medical products shall

be procured at the prices not exceeding those established by the authorized body, except for the unregistered medicines and medical devices, imported into the territory of the Republic of Kazakhstan on the basis of an opinion (permit document), issued by the authorized body.

3. Procurement of medicines and medical devices intended to provide a guaranteed volume of free medical care and medical assistance in the system of compulsory social medical insurance shall be carried out in the manner and by methods, established by the Government of the Republic of Kazakhstan, including through the web portal for the procurement of medicines and medical products.

4. The preemptive right to conclude contracts in the framework of the guaranteed volume of free medical care and in the system of compulsory social medical insurance shall belong to the subjects in the field of circulation of medicines and medical products, including pharmacies with the right to manufacture medicines, having a certificate of compliance of the object with the requirements of:

1) the good manufacturing practice (GMP) in the procurement of medicines and the conclusion of long-term contracts for the supply of medicines;

2) the good distribution practices (GDP) in the procurement of medicines, pharmaceutical services and conclusion of long-term contracts for the storage and transportation of medicines and medical products in the framework of guaranteed volume of free medical care and in the system of compulsory social health insurance;

3) the good pharmacy practice (GPP) in the procurement of pharmaceutical services, accounting services and sales of medicines and medical devices in the framework of the guaranteed volume of free medical care and in the system of compulsory social health insurance.

Footnote. Article 76 is in the wording of the Law of the Republic of Kazakhstan dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2017); as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication); as amended by laws of the Republic of Kazakhstan No. 208-VI dated 28.12.2018 (shall be enforced since 01.01.2020).

Article 77. Single distributor

1. A single distributor shall be determined by the Government of the Republic of Kazakhstan.

The main activities of a single distributor shall be:

- 1) selection of suppliers;
- 2) conclusion of contracts for the supply of medicines and medical devices;
- 3) conclusion of long-term contracts for the supply of medicines and medical devices and (or) for the storage and transportation of medicines and medical devices;
- 4) provision with medicines and medical products according to the list, determined by the authorized body;

5) procurement of medicines and medical devices, services for storage and transportation according to a list, determined by the authorized body;

6) procurement of pharmaceutical services;

7) procurement of services for the accounting and sale of medicines and medical devices;

8) organization of procurement of medical devices within the guaranteed volume of free medical care.

2. The principles of the procurement of medicines and medical devices shall be:

1) the provision of potential suppliers with equal opportunities to participate in the procurement procedure;

2) fair competition among potential suppliers;

3) publicity and transparency of the procurement process;

4) support for domestic producers.

Footnote. Article 77 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 77-1. Powers of a single operator

Single operator shall:

1) conduct the creation, development, maintenance and system maintenance of a web portal for procurement of medicines and medical devices;

2) manage projects for development of a web portal for procurement of medicines and medical devices;

3) provide services to the subjects of health care on the use of a web portal for procurement of medicines and medical devices;

4) provide consulting assistance to the subjects of health care on the functioning of the web portal for procurement of medicines and medical devices;

5) ensure the information security of the storage of electronic information resources of the subjects of the public procurement system, posted on the web portal for procurement of medicines and medical devices;

6) fill the content of the web portal for procurement of medicines and medical devices in accordance with the procedure for organizing and conducting the procurement of medicines and medical devices, pharmaceutical services;

7) interact with the authorized subjects on the issues of integration of information systems of state bodies, state electronic information resources and information security.

Footnote. Chapter 14 shall be supplemented by Article 77-1 in accordance with the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 78. Storage and transportation of medicines and medical devices

1. Medicines and medical devices shall be stored and transported under the conditions ensuring the preservation of their safety, quality and efficacy, in accordance with the rules for

the storage and transportation of medicines and medical devices, approved by the authorized body.

2. It shall be prohibited to extend the shelf life of medicines and medical devices.

3. Subjects in the field of circulation of medicines and medical devices that transport and store medicines must comply with the requirements of the good distribution practice (GDP) or the good pharmacy practice (GPP).

Footnote. Article 78 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 79. Destruction of medicines and medical devices

Medicines and medical products that have become unusable, expired, falsified medicines and medical products and others that do not meet the requirements of the laws of the Republic of Kazakhstan shall be considered unsuitable for sale and medical use and shall be subject to destruction by subjects in the field of circulation of medicines and medical products in whose possession they are, in the manner determined by the authorized body.

Footnote. Article 79 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 80. Procedure of importation of medicines and medical devices into the territory of the Republic of Kazakhstan

1. Importation into the territory of the Republic of Kazakhstan of medicines and medical devices shall be carried out in the manner, determined by the authorized body in accordance with the customs legislation of the Republic of Kazakhstan and (or) the Eurasian Economic Union.

2. It shall not be allowed to import into the territory of the Republic of Kazakhstan the medicines and medical devices that have not passed the state registration in the Republic of Kazakhstan, except for the cases specified in paragraph 3 of this article and article 80-2 of this Code.

3. It shall be allowed to import medicinal products and medical devices not registered in the Republic of Kazakhstan to the territory of the Republic of Kazakhstan on the basis of a conclusion (permit document), issued by the authorized body if they are intended for:

1) conduct of clinical studies;

2) expert examination of medicinal products and medical devices during the state registration, re-registration and introduction of changes to the registration dossier;

3) the state registration of medicines and medical devices;

4) medical care for the life of a particular patient or medical care for a limited number of patients with rare and (or) very severe pathology with the possibility of medical use and procurement;

5) exhibitions without the right for their further sale;

6) prevention and (or) elimination of consequences of emergency situations;

7) introduction of innovative medical technologies;

8) procurement by a single distributor of medicines and medical devices supplied by international organizations, established by the General Assembly of the United Nations Organization and (or) prequalified by the World Health Organization, except for the medicines and medical devices under long-term contracts for the supply of medicines and medical products;

9) the use as a component, included in the composition or structure of a medical device and not intended for independent use outside the composition or structure of the medical device.

4. It shall be prohibited to import into the territory of the Republic of Kazakhstan the medicines and medical devices as humanitarian aid that have not passed the state registration, except for certain cases, determined by the authorized body.

Medicines and medical products (including unregistered), intended for humanitarian aid (assistance) or assistance in emergency situations, shall be imported into the Republic of Kazakhstan on the basis of a conclusion (permit document), issued in the manner, determined by the authorized body.

5. Medicinal products and medical devices imported into the territory of the Republic of Kazakhstan that do not comply with the requirements of the legislation of the Republic of Kazakhstan in the field of health care shall be confiscated and destroyed.

Footnote. Article 80 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 80-1. Persons authorized to import medicines and medical devices to the territory of the Republic of Kazakhstan

Import of medicines and medical products into the territory of the Republic of Kazakhstan in the manner, determined by the authorized body can be carried out:

1) by the subjects in the field of circulation of medicines and medical devices that are licensed to manufacture medicines and medical devices;

2) by the subjects in the field of circulation of medicines and medical devices that are licensed to wholesale the medicines or are included in the register of healthcare subjects, engaged in the wholesale of medical devices, upon notification of the commencement of activities;

3) by the research organizations, laboratories for development and state registration of medicines and medical devices in accordance with this Code;

4) by foreign manufacturers of medicines and medical devices, their authorized representative offices (branches) or their trusted individuals and legal entities for examination during the state registration, clinical studies and (or) tests and for participation in exhibitions of manufacturers of medicines and medical devices in the Republic Kazakhstan;

5) healthcare organizations for medical activities.

Footnote. Chapter 14 shall be supplemented by Article 80-1 in accordance with the Law of the Republic of Kazakhstan dated 21.06.2013 No. 107-V (shall be enforced upon expiry of thirty calendar days after its first official publication); in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 80-2. Import of medicinal products and medical devices, as well as biological material of preclinical (non-clinical) and clinical studies, standard samples of pharmaceutical substances (active pharmaceutical substances) and their impurities into the territory of the Republic of Kazakhstan for personal use and other non-commercial purposes

1. Medicines and medical devices shall be imported into the territory of the Republic of Kazakhstan without the permission of the authorized body, if they are intended for:

1) personal use by individuals, employees of the diplomatic corps or representatives of international organizations;

2) treatment of passengers and crew members of vehicles, train crews and drivers of vehicles who arrived on the customs territory of the Eurasian Economic Union;

3) treatment of participants in international cultural and sports events and participants in international expeditions.

2. In the cases provided for by paragraph 1 of this article, the import into the territory of the Republic of Kazakhstan of medicines and medical devices not registered in the Republic of Kazakhstan shall be allowed.

3. The biological material of preclinical (nonclinical) and clinical studies, standard samples of pharmaceutical substances (active pharmaceutical substances) and their impurities shall be imported into the territory of the Republic of Kazakhstan without the permission of an authorized body.

4. Import of biological material of preclinical (non-clinical) and clinical studies, standard samples of pharmaceutical substances (active pharmaceutical substances) and their impurities into the territory of the Republic of Kazakhstan shall be carried out:

1) by manufacturers of medicines and medical devices;

2) by foreign manufacturers of medicines and medical devices, their authorized representative offices (branches) or their trusted individuals and legal entities;

3) by research organizations, laboratories in the field of health care, education and science

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); in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 80-3. Interaction of the authorized body and the authorized body in the customs area

1. When moving medicines and medical devices through the customs border of the Eurasian Economic Union, which coincides with the State Border of the Republic of Kazakhstan, the authorized body in the customs area should provide information, confirmed by the authorized body, on the state registration of each imported medicinal products and medical devices with the date and number of the state registration, except for the cases, stipulated in paragraphs 3 and 4 of article 80 and article 80-2 of this Code.

2. The authorized body in the customs area shall submit to the authorized body the information on import of medicines and medical devices into the territory of the Republic of Kazakhstan through the customs border of the Eurasian Economic Union, which coincides with the State border of the Republic of Kazakhstan, and export of medicines and medical devices from the territory of the Republic of Kazakhstan through the customs border of the Eurasian Economic Union, coinciding with the State border of the Republic of Kazakhstan,.

Footnote. Chapter 14 shall be supplemented by Article 80-3 in accordance with the Law of the Republic of Kazakhstan dated 21.06.2013 No. 107-V (shall be enforced upon expiry of thirty calendar days after its first official publication); in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 81. Procedure of export of medicines and medical devices, as well as biological material of preclinical (non-clinical) and clinical studies, standard samples of pharmaceutical substances (active pharmaceutical substances) and their impurities from the territory of the Republic of Kazakhstan

1. Export of medicines and medical devices from the territory of the Republic of Kazakhstan shall be carried out in the manner, determined by the authorized body.

2. Medicines and medical devices may be exported from the territory of the Republic of Kazakhstan without the consent of the authorized body:

1) for personal use of individuals, leaving the territory of the Republic of Kazakhstan, in the quantity necessary for the course of treatment;

2) in the first-aid kit of a vehicle, leaving the territory of the Republic of Kazakhstan for the treatment of passengers;

3) exhibition samples, imported with the permission of an authorized body for holding exhibitions;

4) medical devices, imported for preclinical (non-clinical) or clinical research.

3. Export of medicines and medical devices from the territory of the Republic of Kazakhstan as part of the material and technical means of medical and emergency rescue organizations and groups, leaving the territory of the Republic of Kazakhstan to participate in emergency response shall be carried out in the manner determined by the authorized body.

4. Biological materials of preclinical (nonclinical) and clinical studies, standard samples of pharmaceutical substances (active pharmaceutical substances) and their impurities can be

exported from the territory of the Republic of Kazakhstan without the permission of the authorized body.

5. Export from the territory of the Republic of Kazakhstan of biological material of preclinical (non-clinical) and clinical studies, standard samples of pharmaceutical substances (active pharmaceutical substances) and their impurities shall be carried out:

- 1) by manufacturers of medicines and medical devices;
- 2) by foreign manufacturers of medicines and medical devices, their authorized representative offices (branches) or their trusted individuals and legal entities;
- 3) by research organizations, laboratories in the field of health care, education and science

Footnote. Article 81 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Chapter 15. General requirements for safety of medicines and medical devices

Footnote. Chapter 15 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 82. Installation, repair, technical and metrological maintenance of medical devices

1. Installation, repair, maintenance and metrological maintenance of medical devices shall be carried out by individuals or legal entities, entitled to perform these works, in accordance with the legislation of the Republic of Kazakhstan.

2. The safety level of medical devices after repair must not be lower than the safety level, established by the technical passport of medical devices.

3. The organization of the metrological provision of medical measuring instruments operated in health care organizations shall be regulated in accordance with the legislation of the Republic of Kazakhstan on ensuring the uniformity of measurements.

4. A medical device that is a measuring instrument shall be subject to inclusion in the register of the state system for ensuring the uniformity of measurements of the Republic of Kazakhstan and shall be allowed for use in accordance with the legislation of the Republic of Kazakhstan on ensuring the uniformity of measurements.

The list of medical devices that are the measuring instruments shall be approved by the authorized body in coordination with the authorized state body implementing the state regulation in the field of technical regulation and metrology.

Article 83. Classification of safety and reclassification of safety of medical devices, depending on the degree of potential risk of use

1. Medical products used in the Republic of Kazakhstan shall be divided into classes depending on the degree of potential risk of use and on the types in accordance with the nomenclature of medical products of the Republic of Kazakhstan.

2. Rules for classification of medical devices, depending on the degree of potential risk of use, shall be approved by the authorized body.

3. A class of medical products according to the degree of potential risk of use shall be approved during the state registration by an authorized body. Each medical device can be assigned to one class only.

4. The order of formation and maintenance of the nomenclature of medical products of the Republic of Kazakhstan shall be determined by the authorized body.

5. The authorized body may make changes to the classification based on a detailed recording of the principles, phenomena, medical methods, forming the basis of the work of medical devices.

Article 84. Suspension, prohibition or withdrawal from circulation or restriction of the use of medicines and medical devices

1. The authorized body may suspend or prohibit the use, sale or production of medicines and medical devices, as well as decide on withdrawal from circulation or restriction of the use in the cases of:

1) non-compliance of medicines and medical devices with the requirements of the legislation of the Republic of Kazakhstan in the field of health care;

2) revelation of adverse reactions of medicinal products hazardous to human health, not indicated in the instructions for medical use of the medicinal product, or increasing the frequency of revelation of cases of serious adverse reactions specified in the instructions, or low therapeutic efficacy (absence of therapeutic effect), or the availability of information on suspending and (or) withdrawing it from the market of other countries due to the revelation of serious adverse reactions with an unfavorable “benefit-risk” ratio;

3) in the process of applying medical devices, revelation of design defects, principles of operation, production performance, affecting the safety of their use;

4) violations of the approved process for the production of medicines and medical devices, affecting the safety, quality and effectiveness of their use;

5) availability of data on the harm to the health of a patient or a consumer in connection with the use of medicines and medical devices;

6) reception of data on the insufficiency of the scientific and technical level of production technology and quality control, ensuring a reduction in the safety level of the use of medicines and medical devices;

7) the appeal of the holder of the registration certificate about suspension, revocation of the registration certificate or withdrawal from circulation or restriction of the use of a medicinal product and a medical device;

8) non-compliance of medicines with the requirements of the good pharmaceutical practices of the Republic of Kazakhstan and (or) the Eurasian Economic Union, identified following the results of the pharmaceutical inspection;

9) failure to fulfill the pharmacovigilance obligations by the holder of the registration certificate of the medicinal product and the manufacturer of the medical device for monitoring the safety, quality and efficacy of medical devices.

2. The rules of suspension, prohibition or withdrawal from circulation or restriction of the use of medicines and medical devices shall be approved by the authorized body.

Article 84-1. Counterfeit medicines and medical devices

1. The production, import, storage, use and sale of counterfeit medicines and medical devices in the Republic of Kazakhstan shall be prohibited.

2. Counterfeit medicines and medical devices shall be destroyed in the manner, determined by the authorized body.

3. Subjects in the field of circulation of medicines and medical devices for the production, storage, distribution, marketing of counterfeit medicines and medical devices shall be responsible in accordance with the laws of the Republic of Kazakhstan.

4. The falsification of medicines and medical devices (submission of false information about the characteristics and (or) the source of origin) shall also include the accessories, parts and materials, manufactured and intended for production of counterfeit products.

5. Preventing and combating the falsification of medicines and medical devices shall be carried out by the authorized body together with the interested government agencies, organizations of manufacturers of medicines and medical devices, subjects of health care and public organizations.

6. The authorized body shall carry out international cooperation in the fight against counterfeit medicines and medical devices.

Article 85. Pharmacovigilance and monitoring of safety, quality and efficacy of medical devices

1. The authorized body shall ensure the functioning of the pharmacovigilance system and monitor the safety, quality and efficacy of medical devices in the Republic of Kazakhstan.

2. The state expert organization in the field of circulation of medicines and medical devices in order to ensure the protection of public health and improve patient safety shall carry out:

collecting, analyzing, evaluating and verifying the reports of adverse reactions of medical product, adverse events (incidents) of a medical product, coming from the subjects of health care and in the field of circulation of medicines and medical products, consumers;

assessment of the ratio "benefit-risk" of medicines and medical devices based on the pharmacovigilance and monitoring of the safety, quality and efficacy of medical devices in the Republic of Kazakhstan, data, provided by holders of registration certificates of medicines, manufacturers of medical devices, data, received from other sources.

3. The procedure for pharmacovigilance and monitoring of the safety, quality and efficacy of medical devices shall be determined by the authorized body.

4. Pharmacovigilance and monitoring of the safety, quality and efficacy of medical devices shall be carried out by the subjects of health care, subjects in the field of circulation of medicines and medical devices, as well as holders of registration certificates for medicines and manufacturers of medical devices, organizations for the maintenance of medical devices.

5. Subjects of health care shall be obliged to inform the authorized body in writing and in a timely manner about the facts of undesirable reactions, including those not indicated in the instructions for the use of a medical product, about the peculiarities of interaction of the medicine with other medicines, overdose, drug dependence, abuse, absence or low efficacy of the medicine and about the adverse events (incidents) of medical devices.

The holder of the registration certificate of the medicinal product and the manufacturer of the medical device shall be required to fully provide the authorized body with information on the safety of the medicinal product, as well as to inform the authorized body in a timely manner about the occurrence of undesirable reactions and (or) adverse events (incidents) when using the medicinal product or medical device.

6. The authorized body shall take into account the data of pharmacovigilance and monitoring of the safety, quality and effectiveness of medical devices in other countries when making decisions on suspension, prohibition or withdrawal from circulation or restriction of the use of medicines and medical devices in the Republic of Kazakhstan.

Article 86. Information on medicines and medical devices

Information on medicines and medical devices, approved for the application and use on the territory of the Republic of Kazakhstan, on medicinal products that have not passed the state registration, do not meet the requirements of the legislation of the Republic of Kazakhstan in the field of health care, on withdrawal of the decision on state registration, as well as on medicinal products, prescribed by a doctor, shall be published in the specialized publications for medical and pharmaceutical workers.

Article 86-1. State regulation of prices for medicines or medical products

1. State regulation of prices shall be applied to the medicinal products, registered and circulating in the Republic of Kazakhstan in accordance with the rules for regulating the prices of medicinal products, approved by the authorized body.

2. The authorized body, not more than once every six months, not later than the tenth day of the month following the reporting half year, shall approve the marginal prices for the trade name of the medicinal product for retail and wholesale sales, indicating the method of their calculation, information about the data on which the price is formed.

3. The authorized body shall approve the marginal price for a trade name of a medicinal product or a medical device in the framework of the guaranteed volume of free medical care and in the system of compulsory social health insurance, the marginal price on the international non-proprietary name of the medicinal product or the technical characteristics of

a medical product within the guaranteed volume of free medical care and in the system of compulsory social health insurance.

4. The authorized body, on an ongoing basis, shall keep records and systematize the information, specified in paragraphs 2 and 3 of this article in electronic form in chronological order, taking into account the changes made and saving the previous versions, with the possibility of open access to this information on its Internet resource.

The information, specified in paragraphs 2 and 3 of this article, shall be kept for five years, starting with the year following the year when the marginal prices for medicines are approved.

Footnote. Chapter 15 shall be supplemented with Article 86-1 in accordance with the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of three months after its first official publication).

Article 86-2. Rational use of medicines

1. The rational use of medicines shall be carried out to improve the quality of medical care and the results of treatment by developing a formulary system.

2. The formulary system shall ensure the optimal use of safe, effective, affordable medicines. The activity of the formulary system shall be carried out in the manner, determined by the authorized body.

3. Health care organizations shall ensure the rational use of medicines, the training of clinical pharmacologists, clinical pharmacists and regular professional development of health care specialists in the rational use of medicines.

Article 86-3. Ethical promotion of medicines and medical devices

1. Ethical promotion of medicines and medical devices shall be the activity carried out in the process of promoting safe, high-quality and effective medicines and medical devices from the developer and (or) manufacturer of a medicinal product or a medical device prior to the consumer, based on fair competition and responsibility of all parties involved.

2. Ethical promotion of medicines and medical devices shall be carried out in the manner determined by the authorized body.

3. For the rational use of medicines and medical devices, subjects of health care, members of professional associations, and subjects in the field of circulation of medicines and medical devices must comply with the following conditions for the ethical promotion of medicines and medical devices:

1) promotion of medicines and medical devices on the market should ensure the completeness and accuracy of the information provided in relation to the safe, high-quality and effective medicines and medical products;

2) patients, pharmaceutical and medical specialists should receive the necessary and accessible information about medicines and their side effects;

3) promotion of medicines and medical devices on the market should be objective with the ethical standards and shall be carried out in accordance with the requirements of the legislation of the Republic of Kazakhstan in the field of health care;

4) the information and data contained in the advertisement must be reliable and scientifically confirmed.

4. Medical specialists, prescribing the medicines, shall be prohibited from participating in the advertising of medicines and medical devices, as well as recommending patients the certain retail sales of medicines and medical products for the purpose of personal interest in receiving remuneration for their services.

Medical specialists shall be obliged to make prescriptions for medicines within their competence if there are appropriate medical indications under the international non-proprietary name, except for the cases of the patient's individual intolerance.

Specialists of the retail sales of medicines and medical devices when selling medicines should offer the buyer (patient) all available medicines that match the prescription, indicating all available ones, their cost and features of use.

5. In the medical organizations and educational organizations in the field of health care, it shall be prohibited to promote medicines and medical devices by representatives of manufacturers of medicines and medical devices and (or) distributors, except for the holding of daily medical conferences, scientific conferences and (or) specialized seminars.

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) provision of medicines and medical devices within the guaranteed volume of free medical care and in the system of compulsory social health insurance, including for certain categories of citizens with certain diseases (conditions), free and (or) subsidized medicines, medical devices, and specialized medical products at the outpatient level in accordance with the list approved by the authorized body;

3) choice of a medical organization, including on the conditions established by the Law of the Republic of Kazakhstan "On Compulsory Social Health Insurance", high-quality and timely medical care;

4) additional medical services in excess of the guaranteed volume of free medical care and medical care in the compulsory social health insurance system at the expense of its funds, funds of the organizations themselves, the voluntary medical insurance system and other non-prohibited sources;

4-1) co-payment ;

5) receiving medical assistance abroad at the expense of budgetary funds in the presence of evidences in the manner determined by the authorized body;

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.

12) voluntary will for the possibility of withdrawing after death of tissues (parts of tissue) and (or) organs (parts of organs) for the purpose of transplantation.

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) medical examinations within the guaranteed volume of free medical care and in the system of compulsory social health insurance, dynamic observation 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. Persons with sexual identity disorders, except for the persons with mental disorders (diseases), shall have the right to change their gender.

The rules for medical examination and sex change for the persons with sexual identity disorders shall be established by the authorized body.

4. Citizens, whose freedom is limited, as well as the persons, serving sentence on the verdict of the court in places of deprivation of liberty, placed in special institutions, shall receive medical assistance in the manner determined by the bodies of the penal system, in agreement with the authorized body. These persons shall enjoy all the above rights of citizens of the Republic of Kazakhstan when they receive medical assistance.

5. Oralman, foreigners and stateless persons permanently residing in the territory of the Republic of Kazakhstan shall have the right to receive a guaranteed volume of free medical care on an equal basis with the citizens of the Republic of Kazakhstan.

Oralman, foreigners and stateless persons temporarily staying in the Republic of Kazakhstan shall be entitled to receive a guaranteed volume of free medical care for acute diseases that are dangerous to others, in accordance with a list, determined by the authorized body, unless otherwise provided by the laws and international treaties, ratified by the Republic of Kazakhstan.

5-1. Refugees, as well as asylum seekers, shall be provided with preventive, diagnostic and therapeutic medical services that have the greatest proven effectiveness, in the manner and in the volume, determined by the authorized body;

6. Is excluded by the Law of the Republic of Kazakhstan dated 29.09.2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2016); dated 30.06.2017 No. 80-VI ((see Art. 2 for the enactment procedure); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten 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 dynamic observation, treatment, drug provision, health improvement and vaccination within the guaranteed volume of free medical care and in the system of compulsory social health insurance;
 - 4) reception of a palliative care and nursing 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 center and 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. Children with disabilities, as well as HIV-infected people shall have the right to receive free medical and pedagogical correctional support in educational and healthcare organizations in accordance with the legislation of the Republic of Kazakhstan in the field of 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.

Footnote. Article 89 as amended by laws of the Republic of Kazakhstan No. 80-VI dated 30.06.2017 (shall be enforced since 01.01.2020); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication);

Article 90. Duties of citizens, individual entrepreneurs and legal entities

1. Citizens shall be obliged to:
 - 1) to take care of preserving one's health, to bear joint and several responsibility for preservation and strengthening of individual and public health;

1-1) pay contributions to compulsory social health insurance in accordance with the Law of the Republic of Kazakhstan "On Compulsory Social Health Insurance";

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) conduct sanitary and anti-epidemic and sanitary-preventive measures;

2) comply with the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of population and hygienic standards, as well as acts and sanitary and epidemiological conclusions of officials, performing state sanitary and epidemiological control and 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) to inform the authorized body in a timely manner about the cases of revelation of adverse reactions, the absence and (or) low effectiveness of medicines and revelation of adverse events (incidents) of medical products;

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) prevent persons from the work, who do not have a document, certifying the passage of medical examination, hygienic training, as well as to exclude from work those with infectious and parasitic diseases and carriers of infectious and parasitic pathogens, identified by healthcare 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.

16) provide complete and reliable information about the medicines they sell;

17) pay deductions and (or) contributions to compulsory social health insurance in accordance with the Law of the Republic of Kazakhstan "On compulsory social health insurance".

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); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 16.11.2015 No. 406-V (shall be enforced from 01.07.2017); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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) choice or replacement of a doctor or medical organization, including a foreign doctor, working in healthcare organizations of the Republic of Kazakhstan, providing medical assistance within the guaranteed volume of free medical care;

3-1) notification that audio and (or) video surveillance and recording shall be conducted in the 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. The patient shall have the right to receive information about his rights and responsibilities, the services provided, the cost of paid services, the order of their provision, taking into account the availability for people with visual impairment and (or) hearing. Information on the rights of the patient should be placed in the places of visual agitation of 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 should be provided after receiving informed oral or written voluntary consent from the patient. Written voluntary consent of the patient for invasive interventions shall be made in the form approved by the authorized body.

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.

Footnote. Article 91 as amended by the laws of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 03.12.2015 No. 433-V (shall be enforced from 01.01.2016).

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;
- 8) perform all instructions prescribed when receiving medical and medicinal assistance at an outpatient level, in accordance with the contract concluded with the medical organization.

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.

Footnote. Article 92 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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) when there is a threat of spreading of diseases that pose a danger to others, including the blood donation and its components;

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;

6) when a citizen has a mental disability and a tendency to sexual violence;

7) during the monitoring of contractual obligations on the quality and volume of medical services.

4-1. It is not a matter of disclosure of a medical secret to transfer a reserve copy of an electronic information resource for storage to a single platform for the backup storage of electronic information resources in accordance with the procedure and terms determined by the authorized body in the field of information security, unless such electronic information resources contain information related to reconnaissance, counterintelligence activities and security measures to ensure the safety of protected persons and objects, the transfer of which shall be carried out in accordance with the legislation of the Republic of Kazakhstan on state secrets.

5. Without the permission of individuals (patients), it shall be prohibited to collect and process personal data, relating to their privacy to form electronic information resources, containing personal data of individuals (patients), except for the cases involving donation of blood and its components, tissues, organs.

It shall not be allowed to connect electronic information resources, containing personal data of individuals (patients) to telecommunication networks that connect them to other databases without the permission of individuals (patients) when using personal data, relating to their private life, except for the cases, involving donation of blood and its components, tissues, organs, as well as requests from law enforcement, special state and other bodies for provision of information in the form of an electronic document, constituting medical secrecy, about the status of dispensary registrations of people, suffering from socially dangerous disorders and diseases, including persistent mental disorders, alcohol, drugs and other types of addiction, tendency to aggression and violent acts.

For illegal collection and processing of personal data concerning the private life of individuals (patients), officials shall be liable under the laws of the Republic of Kazakhstan.

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); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days

after its first official publication); dated 24.11.2015 No. 419-V (shall be enforced from 01.01.2016); dated 09.04.2016, No. 501-V (shall be enforced from 01.01.2018); dated 28. 12. 2017 No. 128-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days 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, tissues of reproductive organs;
 - 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, tissues of reproductive organs, embryos.
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.

Footnote. Article 96 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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, consulting assistance to pregnant women, women in labor, and parturient women in health care entities shall be provided within the guaranteed volume of free medical care and in the system of compulsory social health insurance.

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.

Footnote. Article 97 as amended by Law of the Republic of Kazakhstan No. 80-VI dated 30.06.2017 (shall be enforced since 01.01.2020).

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. Is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Footnote. Article 98 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 99. The auxiliary reproductive techniques and technologies, cloning

1. A woman and a man, both married and unmarried, shall have the right to use assisted reproductive methods and technologies if they have mutual informed voluntary consent to medical intervention. A single woman also shall have the right to use assisted reproductive methods and technologies if she has her informed voluntary written consent for medical intervention.

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. The human embryo cannot be used for commercial, military and industrial purposes.

5. Human cloning - reproduction of genetically identical individuals shall be prohibited in the Republic of Kazakhstan.

6. Export from the Republic of Kazakhstan of sex cells, human embryos for commercial, military or industrial purposes shall not be allowed.

Footnote. Article 99 as amended by the laws of the Republic of Kazakhstan dated 03.07.2014 No. 227-V (shall be enforced from 01.01.2015); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 100. Health care for surrogacy

1. Surrogate motherhood - bearing and birth of a child (children), including cases of premature birth, under a contract between a surrogate mother and spouses with payment of remuneration.

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.

Footnote. Article 100 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 101. Donation of sexual cells, tissues of reproductive organs

1. Citizens between the ages of eighteen and thirty-five years old, physically and mentally healthy, who have undergone a medical genetic examination, shall have the right to be donors of sex cells, tissues of reproductive organs.

2. Donors shall have no right to information about the future fate of their donor sex cells, the tissue of reproductive organs.

3. The procedure and conditions for carrying out the donation of germ cells, tissues of reproductive organs shall be determined by the authorized body.

Footnote. Article 101 is in the wording of the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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 103-1. Chemical castration

1. Chemical castration - taking drugs that reduce sexual desire, carried out on the basis of a court decision by a medical organization.

2. The type of the used medicinal product, the frequency of its introduction within the period of validity of criminal-legal effect, established by the court, as well as the procedure for applying this measure shall be determined by the authorized body in agreement with the General Prosecutor's Office and the Ministry of Internal Affairs of the Republic of Kazakhstan.

Footnote. Chapter 17 is supplemented by Article 103-1 in accordance with the Law of the Republic of Kazakhstan dated 09.04.2016 No. 501-V (shall be enforced from 01.01.2018).

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. The state shall guarantee the patients with tuberculosis:

- 1) the medical care and drug provision within the guaranteed volume of free medical care;
- 2) social and legal protection;
- 3) non-admission of any forms of discrimination due to the nature of the disease;
- 4) implementation of preventive measures to reduce the incidence of severe, acutely progressive forms of tuberculosis among children.

2. The patients with infectious tuberculosis shall be subject to mandatory hospitalization, treatment and rehabilitation.

Footnote. Article 105 as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 106. The procedure for recognizing a citizen as a contagious TB patient

1. Recognition of a citizen as sick with an infectious form of tuberculosis shall be carried out on the basis of the conclusion of the health organization, taking into account the results of laboratory tests.

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.

Footnote. Article 106 as amended by Law of the Republic of Kazakhstan No. 208-VI dated 28.12.2018 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

Article 107. Grounds and procedure for sending citizens with tuberculosis to compulsory treatment

1. Compulsory treatment of citizens with tuberculosis shall include an anti-tuberculosis and symptomatic treatment with isolation of patients in specialized anti-tuberculosis organizations and shall be carried out at the expense of budget funds.

2. The grounds for compulsory treatment of citizens with tuberculosis shall be:

1) refusal of a patient with tuberculosis, confirmed by a laboratory method, from treatment and the lack of a positive result from all the methods of persuasion (psychological consultation, the use of health education methods), recorded in the medical documentation of the patient;

2) unauthorized leave and violation of the treatment regimen in the form of an unreasonable non-taking of seven daily doses of anti-tuberculosis drugs during the calendar month, recorded in the medical documentation of the patient.

3. Patients with tuberculosis, who have been subjected to compulsory treatment, after discharge from a specialized tuberculosis organization, shall be required to register in the anti-tuberculosis organization at the place of residence.

The procedure for rendering medical assistance to the patients with tuberculosis sent for compulsory treatment shall be determined by the authorized body.

4. The decision on the compulsory treatment of citizens suffering from tuberculosis and evading treatment shall be made by the court at the request of the health care organizations in accordance with the legislation of the Republic of Kazakhstan.

Footnote. Article 107 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 108. Rights of patients with tuberculosis, being under compulsory treatment

Footnote. Title of Article 108 as amended by the Law of the Republic of Kazakhstan dated 06. 04. 2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

1. Patients, suffering from tuberculosis, being under compulsory treatment shall enjoy all the rights of citizens of the Republic of Kazakhstan with restrictions related to the need to adhere the regime of stay in a specialized anti-tuberculosis organization.

2. Sending to compulsory treatment in a specialized anti-TB organization shall not entail a criminal record.

3. The place of work shall be saved for a person, suffering from tuberculosis, directed on 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 remained for the patients, suffering from tuberculosis, directed to compulsory treatment, living in a dwelling of the public housing stock, for the period of stay in treatment.

Footnote. Article 108 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 109. Treatment and maintenance of tuberculosis patients in specialized anti-tuberculosis organizations

Footnote. Article 109 shall be excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 110. Medical supervision and treatment of patients with tuberculosis after the end of compulsory treatment

Footnote. Article 110 is excluded by Law of the Republic of Kazakhstan No. 208-VI dated December 28, 2018 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

Article 111. Social assistance to the patients, suffering from tuberculosis

Footnote. Title of Article 111 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Local executive bodies shall assist patients with tuberculosis, discharged from a specialized anti-tuberculosis medical organization after the end of compulsory treatment, in their work and household arrangements.

Footnote. Article 111 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Chapter 19. PROVISION OF MEDICAL AND SOCIAL ASSISTANCE TO THE HIV-INFECTED

Footnote. The title of Chapter 19 as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 112. State guarantees in prevention, diagnosis and treatment of HIV infection

The state shall guarantee the HIV-infected citizens of the Republic of Kazakhstan, oralmans, foreigners and stateless persons permanently residing in the territory of the Republic of Kazakhstan:

- 1) medical care and drug provision within the guaranteed volume of free medical care;
- 2) ensuring the dynamic monitoring, provision of psychosocial, legal and medical advice;
- 3) social and legal protection;
- 4) non-admission of any forms of discrimination due to the nature of the disease;
- 5) implementation of preventive measures to reduce the risk of HIV transmission from mother to fetus and child.

Footnote. Article 112 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 113. Social protection of HIV-infected persons

1. HIV-infected persons shall be provided with education in educational institutions.
2. Infringement of the rights and legitimate interests of the HIV-infected persons, as well as infringement of housing and other rights and the interests of their close relatives shall not be allowed.

Health care specialists, infected with HIV, who perform medical procedures, related to the violation of the integrity of the skin or mucous membranes, must be transferred to another job that is not related to the violation of the integrity of the skin or mucous membranes.

3. HIV-infected persons, infected as a result of improper performance of their duties by medical specialists and workers in the consumer services sector, shall be entitled to receive compensation for harm caused to life or health, in accordance with the legislation of the Republic of Kazakhstan.

Footnote. Article 113 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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 to protect against HIV infection through sexual contact, through blood and from mother to fetus and child;
- 5) establishment of trust centers, friendly offices for provision of psychological, legal and medical advice;
- 6) ensuring security in provision of services to the population, related to the violation of the integrity of the skin and mucous membranes.

Footnote. Article 114 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 115. Testing for HIV

1. Citizens of the Republic of Kazakhstan, oralmans, foreigners and stateless persons permanently residing in the territory of the Republic of Kazakhstan shall have the right to voluntary anonymous and (or) confidential medical examination and counseling on HIV infection issues free of charge in the manner, determined by the authorized body.

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) persons on the basis of requests of the prosecutor's office, investigation and court;
- 3) persons for clinical and epidemiological indications in accordance with the rules approved by the authorized body.

3. Employees of diplomatic, representative and consular missions of foreign states and other persons enjoying diplomatic privileges and immunity in the territory of the Republic of Kazakhstan shall be tested for HIV only with their consent. The proposal on the necessity of their examination shall be agreed in advance by the authorized body with 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); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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.

Recognition of unfitness shall be made by the decision of a medical commission created in a specialized psychiatric medical organization that has a license for the relevant expertise.

In case of disagreement with the commission's decision, it may be appealed to the court.

2. The list of medical psychiatric contraindications for the implementation of certain types of professional activity, as well as works, related to a source of increased danger, shall be approved by the authorized body and reviewed, taking into account the accumulated experience and scientific achievements, at least once every five years.

Footnote. Article 117 as amended by the laws of the Republic of Kazakhstan dated 29.09.2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 29. 09. 2016 No. 479-V (shall be enforced from 01.01.2017).

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 procedure for using money shall be determined by the authorized body.

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.

Footnote. Article 121 as amended by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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 of ten 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 of ten 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 Kazakhstan dated 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 mental disorders (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, recrudescing 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 carried out by a court decision on the basis of a statement of a psychiatric hospital on the need to extend the period of compulsory hospitalization and treatment, where the conclusion of the commission of psychiatrists shall be attached.

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.); dated 31.10.2015 No. 378-V (shall be enforced from 01.01.2016).

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 shall be 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.

4. Protection of the state psychiatric institution of a specialized type with intensive supervision shall be carried out in accordance with the procedure, determined by the Ministry of Internal Affairs of the Republic of Kazakhstan together with the authorized body.

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); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 128. Discharge from the psychiatric hospital

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 measures of a medical nature shall be applied by a court decision in respect of persons who have committed criminal offenses found to be in need of treatment for alcoholism or drug addiction or substance abuse, as well as for the persons, committed an administrative offense and have been found to be ill with chronic alcoholism or drug abuse or substance abuse and evading voluntary treatment.

Footnote. Article 130 as amended by the Law of the Republic of Kazakhstan dated 03.07.2014 No. 227-V (shall be enforced from 01.01.2015).

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 military men, candidates for cosmonauts, astronauts, employees of special state and law enforcement bodies, members of their families and recipients of pension payments for long service

For military men, candidates for cosmonauts, astronauts, employees of special state and law enforcement agencies, members of their families and recipients of pension payments for long service years, medical assistance shall be provided in accordance with the laws of the Republic of Kazakhstan.

Footnote. Article 135 is in the wording of the Law No. 80-VI dated 30. 06. 2017 (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 135-1. Provision of medical assistance to certain categories of civil servants and citizens

Provision of medical assistance to certain categories of civil servants and citizens shall be carried out in accordance with the list approved by the Office of the President of the Republic of Kazakhstan in agreement with the Administration of the President of the Republic of Kazakhstan.

Medical assistance in accordance with this article shall be provided:

- 1) within the guaranteed volume of free medical care in accordance with this Code;
- 2) in the system of compulsory social health insurance in accordance with the Law of the Republic of Kazakhstan "On Compulsory Social Health Insurance";
- 3) at the expense of budgetary funds by type and in amounts determined by the Office of the President of the Republic of Kazakhstan.

Payment for services for the provision of medical care in accordance with subparagraphs 1) and 2) of part two of this article shall be carried out by the social health insurance fund.

The persons specified in the first part of this article shall have the right to receive medical care within the guaranteed volume of free medical care and in the system of compulsory social health insurance in other health care entities.

Footnote. Chapter 22 is supplemented by Article 135-1 in accordance with the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten days after its first official publication); As amended by Laws of the Republic of Kazakhstan No. 80 VI- dated 30.06.2017 (shall come into effect since 01/01/2020).

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 procedure for collection, storage and use of blood and tissues of citizens exposed to ionizing radiation shall be established by the authorized body.

Footnote. Article 136 as amended by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 136-1. Rendering medical assistance to disabled people

Healthcare organizations shall form the conditions for adapting health facilities for their accessibility to the people with disabilities and other low-mobility groups.

Footnote. Chapter 22 is supplemented with Article 136-1 in accordance with the Law of the Republic of Kazakhstan dated 03.12.2015 No. 433-V (shall be enforced from 01.01.2016).

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.

Article 138-1. Rendering medical assistance to athletes and coaches

1. Medical support and medical assistance to athletes and coaches shall be carried out in accordance with the procedure approved by the authorized body in the field of physical culture and sports, in agreement with the authorized body.

2. Athletes who do not undergo medical examination in accordance with the procedure established by the authorized body in the field of physical culture and sports in agreement with the authorized body shall not be allowed to participate in sports competitions.

Footnote. Chapter 22 is supplemented with Article 138-1 in accordance with the Law of the Republic of Kazakhstan dated 03.07.2014 No. 229-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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 death of the brain recorded by the concilium, subject to a written unanimous consent of close relatives and (or) legal representatives in the manner determined by the authorized body.

Footnote. Article 140 as amended by the Law of the Republic of Kazakhstan dated 06. 04. 2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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 procedure and conditions for the commission and transfer of anatomical gift to healthcare organizations shall be determined by the authorized body.

Footnote. Article 142 as amended by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 142-1. Public-private partnership in health care

1. Creation (reconstruction) and operation of healthcare facilities can be carried out through the implementation of public-private partnership projects, including concession projects, in accordance with the legislation of the Republic of Kazakhstan in the field of public-private partnerships and concessions.

2. The operation of a healthcare facility created as a result of the implementation of a concession project (concession facility), along with the concessionaire, can also be carried out by a functional operator.

In this case, the concessionaire shall have the right to reimbursement of costs and receive income for the sale of the goods (works, services) produced as part of the maintenance of the concession object.

3. When implementing concession projects, providing for the conclusion of a concession agreement on the basis of subparagraph 1-1) of paragraph 1 of Article 21-1 of the Law of the Republic of Kazakhstan "On Concessions":

1) the concessor shall transfer the created concession object under an agreement for the gratuitous use of state property to a functional operator for the implementation of functional services in the manner specified by the concession agreement;

2) the concessionaire shall provide maintenance of the concession object in the manner and under the conditions provided for by the concession agreement;

3) the functional operator, determined before the tender for the selection of the concessionaire, shall provide functional maintenance of the concession object in the manner and under the conditions stipulated by the concession agreement.

4. The concession agreement concluded on the basis of subparagraph 1-1) of paragraph 1 of Article 21-1 of the Law of the Republic of Kazakhstan "On Concessions", shall include provisions on the functional operator, as well as the procedure for joint use by the concessionaire and the functional operator of the concession object.

5. The functional operator must have permits provided for by the legislation of the Republic of Kazakhstan for such activities or must receive them before using the concession object in accordance with the intended purpose.

6. The functional operator shall have the right to:

1) exercise the rights in relation to the concession object on the terms provided for by the contract for the gratuitous use of state property, concluded for the purpose of functional maintenance of the concession object;

2) jointly with the concessionaire to use the concession object in the manner and under the conditions stipulated by the concession agreement;

3) exercise other rights in accordance with the laws of the Republic of Kazakhstan.

7. The functional operator must:

1) maintain the profile of the concession object;

2) produce goods and (or) perform work and (or) provide services provided for by the contract for the free use of state property;

3) comply with the environmental and labor legislation of the Republic of Kazakhstan, as well as the legislation of the Republic of Kazakhstan on employment;

4) reimburse the damage caused to the concession object through its fault;

5) comply with the terms of joint use of the concession object with the concessionaire in the manner prescribed by the concession agreement;

6) comply with other requirements and conditions established by the laws of the Republic of Kazakhstan and the contract for the gratuitous use of state property.

Footnote. Chapter 23 as supplemented by Article 142-1 in accordance with Law of the Republic of Kazakhstan No. 287-VI dated December 26, 2019 (shall be enforced since January 1, 2020).

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 in the field of sanitary and epidemiological welfare of the population and its territorial sub-divisions;
- 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.

Footnote. Article 143 as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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 procedure for development and approval of documents of the state system of sanitary and epidemiological regulation shall be approved by the state body in the field of sanitary and epidemiological welfare of population.

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. Normative legal acts in the sphere of sanitary and epidemiological welfare of population, hygienic standards shall be approved by the state body in the field of sanitary and epidemiological welfare of the population and shall be obligatory for execution by all individuals and legal entities, located on the territory of the Republic of Kazakhstan.

7. State bodies when developing and approving normative legal acts, concerning issues in the sphere of sanitary and epidemiological welfare of population shall be obliged to coordinate them with the state body in the field of sanitary and epidemiological welfare of population.

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); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 145. Sanitary and epidemiological requirements

1. The basis of sanitary and epidemiological requirements shall be sanitary rules and hygienic standards, which shall be established for objects and products subject to state sanitary and epidemiological supervision.

2. Sanitary rules shall establish sanitary and epidemiological requirements for facilities subject to state sanitary and epidemiological supervision, and shall contain requirements for:

- 1) the choice of land for the construction of the facility;
- 2) design, construction, reconstruction, repair and commissioning of facilities;
- 3) maintenance and operation of industrial, public, residential and other premises, buildings, structures, equipment, vehicles;
- 4) water supply, sanitation, heat supply, lighting, ventilation, air conditioning of facilities;
- 5) reception, storage, recycling (processing) of raw materials;
- 6) conditions of production, packaging, transportation, storage, sale, disposal and destruction of food products;
- 7) iodization of table salt and enrichment (fortification) of food products;
- 8) conditions of production, packaging, transportation, storage, sale, disposal and destruction of immunological medicines (immuno-biological medicines);
- 9) application and use of potentially hazardous chemical and biological substances (including toxic, radioactive, biological and chemical substances, poisons and toxic substances, biological and microbiological organisms and their toxins, biological agents and materials), disposal, transportation, storage, burial and working conditions with them;
- 10) working conditions with sources of physical factors, affecting the person;

- 11) conditions of industrial production of medicines;
- 12) production for technical purposes;
- 13) goods for household and hygienic purposes and technologies for their production;
- 14) conditions for upbringing, education, living and working practices, physical development, labor, recreation, nutrition, water supply and medical care for various groups of the population;
- 15) training and workload and the mode of study in educational organizations;
- 16) the conditions for sterilization and disinfection of medical devices;
- 17) organization of specialized (children's, dietary and dietary preventive), medical and preventive, public catering services;
- 18) water sources (water intake points for household and drinking purposes), domestic and drinking water supply and places of cultural and domestic water use and safety of water objects;
- 19) collection, use, application, neutralization, transportation, storage and disposal of production and consumption wastes;
- 20) organization and implementation of works and services, including development, testing, production, manufacture, storage, transportation, sale, use of disinfection and disinfestation, equipment, materials, maintenance and operation of disinfection objects, as well as control of the efficiency and safety of operations and services;
- 21) the conditions for transportation of passengers;
- 22) liquidation, conservation, re-profiling of objects;
- 23) implementation of production control;
- 24) working conditions, consumer services, medical support, specialized dietary curative and dietary preventive nutrition;
- 25) hygienic education and training of the population;
- 26) organization and conduct of sanitary and anti-epidemic and sanitary-preventive measures, including implementation of sanitary protection of the territory of the Republic of Kazakhstan, introduction of restrictive measures, including quarantine, against patients with infectious and parasitic diseases, medical examinations, and preventive vaccinations of the population;
- 27) zones of sanitary protection and sanitary-protective zones.

3. Hygienic standards shall establish standards for the maximum permissible concentrations of harmful substances (chemical, biological), physical effects, permissible levels of radiation exposure, compliance with which shall provide a person life-friendly and safe conditions for life.

Hygienic standards shall be established to:

- 1) microclimate, air exchange, air of the working area, physical factors of industrial, residential and other premises, the territory of residential development;

2) radiation, chemical, microbiological, toxicological, parasitological safety of products (goods) and the environment;

3) atmospheric air in urban and rural settlements, on the territories of industrial organizations;

4) physical factors, maximum permissible emissions and maximum permissible discharges of harmful substances into the environment;

5) new types of products, technological equipment, processes.

Footnote. Article 145 as amended by the Law of the Republic of Kazakhstan dated 29.12.2014 No. 269-V (shall be enforced from 01.01.2015); as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 211-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 146. State registration of products, having a harmful effect on human health

1. State registration in the state body in the field of sanitary and epidemiological welfare of population shall be subject to products, having a harmful effect on human health, in accordance with the list and in accordance with the procedure determined by the state body in the field of sanitary and epidemiological welfare of population.

2. State registration of products shall be carried out on the basis of:

1) expert assessment of the impact on the population and environment;

2) sanitary and epidemiological expertise for compliance with regulatory legal acts in the field of sanitary and epidemiological welfare of the population and hygienic standards for the content of substances and individual components of the product;

3) development of special measures, including conditions for utilization and destruction of substances and certain types of products, to prevent their harmful effects on the population and environment.

3. The costs, associated with the conduct of sanitary and epidemiological expertise and scientific justification of products subject to state registration shall be covered by the applicants.

4. A single register of certificates of state registration shall be placed on the Internet resource of the state body in the field of sanitary and epidemiological welfare of the population.

5. The procedure for state registration and withdrawal of a decision on state registration of products, having a harmful effect on human health shall be established by the state body in the field of sanitary and epidemiological welfare of the population.

Footnote. Article 146 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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. Sanitary-epidemiological monitoring shall be carried out by state bodies and organizations of sanitary-epidemiological service in the manner determined by the state body in the field of sanitary-epidemiological welfare of the population.

Footnote. Article 147 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 148. Sanitary and anti-epidemic and sanitary-preventive measures

Footnote. Title of Article 148 is in the wording of the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

1. In order to prevent the emergence and spread of infectious and parasitic diseases, poisonings of the population, sanitary and anti-epidemic and sanitary-preventive measures, stipulated by the documents of the state system of sanitary and epidemiological regulation, shall be carried out, including implementation of sanitary protection of the territory of the Republic of Kazakhstan, introduction of restrictive measures, including number of quarantine, for implementation of production control in relation to patients with infectious and parasitic bubbled diseases, conduct of medical examinations, preventive vaccinations, hygiene education of persons of decreed groups and individuals, engaged in heavy work, work with harmful and (or) dangerous working conditions, underground works.

2. Sanitary-anti-epidemic and sanitary-preventive measures shall be included in the developed documents of the System of state planning of the Republic of Kazakhstan.

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.

5. Hygienic training shall be conducted in order to prevent infectious and parasitic diseases of the decreed population in accordance with the procedure and programs of hygienic training, approved by the state body in the field of sanitary and epidemiological welfare of population.

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); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 30.06.2017 No. 80-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 148-1. Radiation control in the sphere of sanitary and epidemiological welfare of population

1. Radiation control shall be carried out by the state bodies of sanitary and epidemiological service, shall include monitoring of compliance with sanitary and epidemiological requirements to ensure radiation safety of population.

2. Radiation control shall be carried out in the form of an audit, conducted in accordance with the Entrepreneurial Code of the Republic of Kazakhstan.

Footnote. Chapter 24 is supplemented with Article 148-1 in accordance with the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); as amended by the Law of the Republic of Kazakhstan dated 29.10.2015 No. 376-V (shall be enforced from 01.01.2016).

Article 149. Healthcare protection of the territories of the Republic Kazakhstan

1. At the checkpoints across the State border of the Republic of Kazakhstan, coinciding with the customs border of the Eurasian economic union, with the exception of automobile checkpoints, sanitary quarantine points shall be set up to carry out sanitary and quarantine supervision of passengers, crews, train staffs, vehicles, posing a danger to public health.

2. Sanitary and quarantine supervision at the checkpoints (sanitary quarantine points) across the State border of the Republic of Kazakhstan shall be carried out by territorial divisions of the state body in the sphere of sanitary and epidemiological welfare of population

At automobile checkpoints across the State border of the Republic of Kazakhstan, sanitary and quarantine supervision shall be conducted by the state revenue bodies 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 of ten calendar days after its first official publication); dated 07.11.2014 No. 248-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 26. 12. 2017 No. 124-VI (shall be enforced from 01.01.2018).

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 import and spread of infectious and parasitic diseases, the state body in the sphere of sanitary and epidemiological welfare of the population at the

checkpoints across the State border of the Republic of Kazakhstan, coinciding with the customs border of the Eurasian economic union, and in the relevant territories shall impose restrictive measures, including quarantine, with special conditions of entrepreneurial and (or) other activity 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 certain objects shall be introduced (canceled) by the decision of the chief state sanitary doctor of the relevant territory (transport) or his deputies, as well as at departmental objects by the head of structural divisions of other state bodies engaged in activities in the sphere of sanitary and epidemiological welfare of population.

4. The procedure for implementing restrictive measures, including quarantine, and a list of infectious diseases, in case of a threat of occurrence and distribution of which restrictive measures, including quarantine, are introduced, shall be established by the state body in the field of sanitary and epidemiological welfare of population.

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); dated 29.09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 26. 12. 2017 No. 124-VI (shall be enforced from 01.01.2018).

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 by healthcare organizations at the place of their detection, state registration and reporting by state bodies and organizations of sanitary-epidemiological service. The procedure for registering, keeping records of these cases of diseases and poisonings, as well as the procedure for keeping records on them, shall be determined by the state body in the field of sanitary and epidemiological welfare of the population.

2. Cases of infectious and parasitic diseases, occupational diseases and poisonings of the population shall be investigated by specialists of sanitary and epidemiological service in the manner determined by the state body in the field of sanitary and epidemiological welfare of population.

Footnote. Article 151 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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 occurrence of epidemic emergencies, at the expense of budget funds, extraordinary obligatory disinfection, disinsection and deratization shall be carried out according to the decision of local executive bodies of regions, cities of republican significance and the capital upon the recommendation of the state bodies of sanitary and epidemiological services.

2-1. Preventive disinsection and deratization (with the exception of disinsection and deratization on the territory of natural foci of infectious diseases, as well as in the foci of infectious diseases) shall be carried out by local executive bodies of oblasts, cities of republican significance, the capital, the district, the city of regional significance.

3. Focal disinfection, disinfection, deratization on the foci of infectious and parasitic diseases of man and natural foci of infectious and parasitic diseases shall be carried out by the organizations of sanitary and epidemiological service and medical organizations for the purpose of preventing and (or) eliminating infectious and parasitic diseases.

Footnote. Article 152 as amended by the laws of the Republic of Kazakhstan dated 29.09.2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 210-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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, periodic and pre-shift.

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.

Pre-shift mandatory medical examinations shall be carried out in order to establish or confirm the presence or absence of a person's illness, determine the state of health, as well as temporary incapacity for work, professional suitability for work in the intervening shift.

4. The list of harmful factors of production, occupations in which mandatory medical examinations are conducted, as well as the procedure and frequency of these inspections shall be established by the state body in the field of sanitary and epidemiological welfare of the population in agreement with the authorized body.

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. The employers shall not admit to work persons, who have not undergone mandatory medical examinations or are found unfit to work for health reasons, as well as preventive medical examinations within the guaranteed volume of free medical care.

10. The procedure for issuing, registering and maintaining personal medical cards shall be determined by the state body in the field of sanitary and epidemiological welfare of population.

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); dated 29. 12. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 156. Preventive vaccination

1. Individuals on the territory of the Republic of Kazakhstan shall be entitled to receive preventive vaccinations against infectious and parasitic diseases within the guaranteed volume of free medical care.

1-1. Before the introduction of a preventive vaccination, a medical worker shall examine the vaccinated person. The medical worker shall provide him or his legal representative with complete and objective information about preventive vaccination, possible side effects, the consequences of abandoning them, possible post-vaccination complications.

The condition for carrying out a preventive vaccination shall be the availability of consent or refusal in written form..

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 preventive (immunobiological, diagnostic, disinfectant) drugs should be carried out in the order established by the state body in the field of sanitary and epidemiological welfare of population.

4. Is excluded by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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); dated 29. 12. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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 products and alcohol consumption

Footnote. Title of Article 159 is in the wording of the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

1. Prevention and restriction of tobacco products and alcohol consumption shall be aimed at protecting the health of the population, introducing age limit for the persons, eligible to purchase tobacco, alcohol products, forming the attitude of the population towards consumption of tobacco products and alcohol as a factor of increased risk to life and health, conducting agreed measures to prevent the spread of tobacco products and alcohol consumption.

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 buildings and on the territories of healthcare organizations, education, physical culture and sports;

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 information on the composition, the level of tar content, nicotine and at least three harmful compounds - systemic poisons, carcinogenic and mutagenic substances, applied to a pack of tobacco products, packaging of a tobacco product.

The procedure for placing information on the composition, level of tar content, nicotine and systemic poisons, carcinogenic and mutagenic substances on a pack of tobacco products, packaging of a tobacco product, shall be approved by the authorized body;

9) without a warning of the harm of tobacco consumption printed on a pack of tobacco products;

10) without the printed information on prohibition to sell the tobacco products to the persons under eighteen years of age;

11) on a pack of tobacco products, on a package of tobacco products containing the words "low in tar," "light," "very light" or "soft," or other phrases, including in foreign languages, creating a false impression about the less harmfulness of a tobacco product, compared to others and causing associations with fruits, berries, confectionery;

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 the sale of tobacco products is carried out, an inscription "The sale of tobacco products to persons and by persons under the age of eighteen is prohibited" should be placed in a conspicuous place, as well as a warning on the harmful use of tobacco products, approved by the authorized body.

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. Consumption of tobacco products 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 norms provided for in subparagraphs 3), 6), 7) of paragraph 5 of this article shall not be applied in cases, if special equipped places are allotted for the consumption of tobacco products.

7. Places, allotted specifically for the consumption of tobacco products should be equipped in accordance with the requirements, established by the state body in the field of sanitary and epidemiological welfare of the population.

8. The manufacturer and importer of tobacco products shall be obliged to submit reports on the results of laboratory studies on the maximum allowable content of nicotine and tarry substances in all brands of tobacco and tobacco products, the ingredients of tobacco products that they produced, in accordance with the procedure approved by the authorized body, by February 1st, or intend to produce, sell or otherwise distribute in the previous twelve months on the territory 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. It shall be prohibited to import, manufacture, sell and distribute tobacco products, exceeding the maximum permissible levels of nicotine and tar content determined by the state body in the field of sanitary and epidemiological welfare of the population, as well as tobacco products for which sanitary and epidemiological requirements have not been established.

11. Manufacturing, sale and distribution of the goods, imitating tobacco products shall be prohibited.

12. Signs, prohibiting the consumption of tobacco products should be placed in the places, banned for the consumption of tobacco products.

13. A pack of tobacco products, a package of tobacco products should contain a warning about the harmful use of tobacco products, approved by the authorized body and meet the following requirements:

1) to occupy not less than forty percent of each larger area of a pack of tobacco products, packaging of a tobacco product;

2) should not be printed on a transparent wrapping film or any other outer wrapping material;

3) to be made in the form of a picture (pictograms, graphics) and inscriptions.

14. Retail sales shall be prohibited:

1) of alcohol products to the persons under the age of twenty-one;

2) alcohol products, except for sale in restaurants, bars and cafes:

from 23 to 8 o'clock the next day;

with a volume fraction of ethyl alcohol exceeding thirty percent from 21p.m. to 12 a.m. the following day;

3) in other cases, provided by the legislation of the Republic of Kazakhstan.

15. Sponsorship of tobacco, tobacco products and advertising of products, simulating alcoholic beverages shall be prohibited.

It is allowed to render charitable assistance in the order, established by the legislation of the Republic of Kazakhstan, by individuals and legal entities, carrying out importation, production, sale and distribution of tobacco.

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); dated 18. 06. 2014 No. 210-V (shall be enforced upon expiry of twenty-one calendar days after its first official publication); dated 03.07.2014 No. 229-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 No. 299-V (for the procedure of enactment see Article 2).

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 enriching (fortification) of food products shall be determined by the state body in the field of sanitary and epidemiological welfare of population.

Footnote. Article 160 as amended by the Law of the Republic of Kazakhstan dated 29. 09. 2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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 food, fodder salt and other food products subject to mandatory enrichment shall be carried out in accordance with the legislation of the Republic of Kazakhstan on the prevention of iodine deficiency diseases.

Footnote. Article 161 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

SECTION 7. DONATION AND TRANSPLANTATION

Chapter 26. DONATION OF BLOOD AND ITS COMPONENTS

Article 162. Donation of blood, blood banking, its components and preparations

1. The donation of blood and its components shall be the voluntary participation of donors in the protection of public health through the exercise of donor functions.

2. Attraction of donors for implementation of the donor function shall be carried out on a free of charge or on a refundable basis.

Attraction of donors on a refundable basis shall be carried out in the absence of donors who perform the donor function on a free of charge basis.

3. The process of blood banking and its components shall include:

1) donation of blood, which is a single extraction of blood given by the donor;

2) plasma donation, which is a single extraction of blood plasma through plasma exchange method.

Depending on the immune characteristics of the resulting plasma, there shall be:

isoimmune plasma, containing specific protein structures (isoimmune antibodies) in a certain concentration, used to produce blood products and diagnostic reagents;

immune plasma, containing specific protein structures (immune antibodies) of natural or artificial origin in a certain concentration, possessing the property of a targeted therapeutic interaction on certain types of pathogens (immune plasma is used for transfusion into the recipient or for production of blood products);

3) donation of cells, which is a single extraction of blood cells of the donor through the cytopheresis method.

4. In the process of preparation and processing of blood, the following shall be received:

1) blood components that are components of blood, isolated from it in the form of cells and cell-free media;

2) blood products, which are medicines obtained in the processing of blood components.

5. The nomenclature, rules for banking of blood, processing, quality control, storage, sale of blood, its components, as well as the rules for storage and transfusion of blood, its components and preparations shall be approved by the authorized body.

Footnote. Article 162 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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. The safety of donor blood, its components and preparations shall be ensured by complying with the established requirements for donor medical certification and safety and quality in the production of blood products for medical use, approved by the authorized body.

The quality assessment of laboratory tests performed in organizations operating in the blood service field shall be carried out by the republican reference laboratory of the blood service.

2. Is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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.

Footnote. Article 164 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 165. The donor, his rights and obligations

1. A donor shall be an individual, reaching the age of eighteen, who has undergone the appropriate medical examination and having no contraindications, expressing a voluntary desire to donate blood and its components for medical purposes.

2. The donor shall have the right to:

1) donate blood and its components free of charge;

2) donate blood and its components for a fee in the amounts, established by the authorized body;

3) review the results of the medical examination;

4) be encouraged in compliance with this Code.

3. The donor shall be obliged to inform the information known to him about all existing or previous diseases, as well as about the use of narcotic drugs, psychotropic substances, their analogues and precursors.

Footnote. Article 165 as amended by the laws of the Republic of Kazakhstan dated 29.09.2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 03. 07. 2014 No. 227-V (shall be enforced from 01.01.2015); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 166. Medical examination of the donor

1. Before the donation of blood and its components, the donor shall undergo mandatory free medical examination in the manner determined by the authorized body.

2. Health certificates for implementation of donor functions shall be given in public healthcare institutions for free.

Footnote. Article 166 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 167. The guarantees, provided to the donor

1. When performing the donor function on working days, the donor shall be off from work with the average wage saved.

In the event that a gratuitous donation has been made, the donor shall have an additional one day-off with the average wage saved, which can be added to the annual labor leave. These warranties shall be valid for one year from the date of donation.

2. If, by agreement with the employer, an employee who is a donor, commenced work on the days of donation of blood and its components, he shall be provided at his request another day off with preservation of his average salary, or this day may be attached to the annual work holiday.

3. It shall not be allowed to employ an employee who is a donor on the days of donating blood and its components to night work, overtime, hard work, work with harmful and (or) dangerous working conditions.

4. A military man, who is a donor, shall be released from carrying out orders, duty watches and other forms of service during the donation of blood and its components.

5. Students, pupils who are donors, shall be released from educational process during the donation of blood and its components.

6. The system of encouraging donors shall be approved by the authorized body.

Additional incentive measures, provided to the donor, taking into account the total amount of blood and its components donation, shall be determined by normative legal acts of the Republic of Kazakhstan.

7. A donor who made a completed or incomplete donation of blood or its components in the exercise of the donor function free of charge, to replenish the volume of his blood and energy expenditure of the body after donating blood and its components, at his choice, shall receive free food or its monetary equivalent in the amount established by the authorized body.

8. A donor, performing a donor function on a paid basis, the healthcare organization that carries out activities in the field of blood and its components procurement, shall be paid in the manner and amounts established by the authorized body.

Footnote. Article 167 as amended by the laws of the Republic of Kazakhstan dated 29.09.2014 No. 239-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 06.04.2015 № 299-V (shall be enforced upon expiry of ten

calendar days after its first official publication); dated 30.06.2017 No. 80-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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) unhindered free the employee, who is a donor, from work on the day of examination and donation of blood and its 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.

Footnote. Article 168 as amended by the Law of the Republic of Kazakhstan dated 06. 04. 2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Chapter 27. Transplantation of tissues (parts of tissue) and (or) organs (parts of organs)

Footnote. Chapter 27 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 169. Transplantation of tissues (parts of tissue) and (or) organs (parts of organs) and conditions for their removal

1. Donors for the transplantation of tissues (parts of tissue) and (or) organs (parts of organs) may be a person, a human corpse or an animal.

2. Forced removal of tissues (parts of tissue) and (or) organs (parts of organs) of a person and their transplantation shall be prohibited.

3. The purchase and sale of tissues (parts of tissue) and (or) organs (parts of organs) of a person shall be prohibited.

4. A living transplant donor can be a person who is in a genetic relationship with the recipient or has a tissue compatibility with it (the immunological property of organic tissues that promotes their engraftment to the tissues of another organism).

5. A live donor must undergo a comprehensive medical examination and receive a conclusion of a concilium about the possibility for recuperation of his tissue (part of the tissue) and (or) organs (parts of organs).

6. Recuperation of tissues (parts of tissue) and (or) organs (parts of organs) from a person who is a minor or incapable person shall be possible only if the following conditions are simultaneously observed, along with those specified in this article:

1) written notarized consent of his/her legal representatives, who received the necessary information on the state of health in accordance with Article 91 of this Code;

2) absence of another compatible donor who is able to give appropriate consent;

3) the recipient is the donor's brother or sister;

4) transplantation is designed to preserve the life of the recipient;

5) the potential donor does not object to the recuperation.

7. The consent of legal representatives of minors or incapable persons may be withdrawn at any time before the beginning of medical intervention.

8. The recuperation of tissues (parts of tissue) and (or) organs (parts of organs) from a person can be carried out only with his written notarized consent, with the exception of hematopoietic stem cells.

9. For transplantation, only one of the paired organs, part of the organ or tissue may be recuperated, the absence of which does not entail an irreversible health disorder.

10. Recuperation of tissues and (or) organs (parts of organs) from a corpse shall not be allowed, if the healthcare organization at the time of recuperation is informed that during the life the person or his spouse, close relatives or legal representative stated their disagreement on the recuperation of his/her tissues and (or) organs (parts of organs) after the death for transplantation to the recipient.

Tissues and (or) organs (parts of organs) can be recuperated from the corpse for transplantation, if there is indisputable evidence of death recorded by the concilium.

The certification of the death shall be given on the basis of a statement of biological death or irreversible death of the brain (brain death) in the manner determined by the authorized body.

11. The participation of persons, ensuring the recuperation of tissues (parts of the tissue) and (or) organs (parts of organs) for subsequent transplantation, in ascertaining biological death or irreversible death of the brain shall be prohibited.

12. To ensure the transplantation of tissues (part of tissue) and (or) organs (part of organs), the registers of recipients of tissue (part of tissue) and (or) organs (part of organs), as well as donors of tissue (part of tissue) and (or) organs (parts of organs), hematopoietic stem cells shall be formed.

The order of formation and maintenance of registers of recipients of tissue (part of tissue) and (or) organs (part of organs), as well as donors of tissue (part of tissue) and (or) organs (parts of organs), hematopoietic stem cells shall be determined by the authorized body.

13. Determination of the immunological compatibility of tissues during transplantation shall be carried out in the laboratories of immunological typing (HLA-laboratories), functioning as a structural unit at organizations operating in the field of donation of blood, blood banking, its components and preparations.

Determination of the immunological compatibility of tissues during transplantation shall be carried out on the basis of a referral for research from organizations involved in the removal, conservation, preparation, transportation and transplantation of tissues (part of tissue), organs (part of organ).

The HLA-laboratory regulations shall be approved by the authorized body.

Footnote. Article 169 as amended by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 170. The order of transplantation of tissues (parts of tissue) and (or) organs (parts of organs)

1. The medical conclusion on the need for transplantation of tissues (parts of the tissue) and (or) organs (parts of organs) shall be given by the consilium of the relevant healthcare organization.

2. Transplantation of tissues (parts of tissue) and (or) organs (parts of organs) to a recipient who is not capable of making a conscious decision due to his/her state of health shall be performed with the consent of his/her spouse or one of his/her close relatives or legal representatives.

In exceptional cases, when the delay in the transplantation threatens the life of the recipient, and the persons indicated in this paragraph are not available or their location cannot be established, the decision to conduct the transplantation shall be taken by the doctors' concilium, and if it is impossible to assemble it, by the transplant doctor, with the record in the medical documentation and the subsequent notification of this to the officials of healthcare organization within 24 hours.

3. A recipient or legal representative of a minor recipient or recipient recognized as legally incapable by the court should be warned about the possible complications for the recipient's health in connection with the forthcoming transplantation.

4. Transplantation of infected tissues (parts of tissues) and (or) organs (parts of organs) shall be prohibited.

5. Recuperation, conservation, collection, storage, transportation of tissue (part of the tissue) and (or) organs (parts of organs) and transplantation of tissues (parts of tissue) or organs (parts of organs) from a living donor shall be carried out in healthcare organizations included in the List of healthcare organizations in the manner determined by the authorized body and obtained a license for the relevant specialty in accordance with the legislation of the Republic of Kazakhstan.

The list of healthcare organizations for recuperation, collection, storage, conservation, transportation of tissues (parts of tissue) and (or) organs (parts of organs) and tissue transplantation (parts of tissue) or organs (parts of organs) shall be formed in the manner determined by the authorized body.

6. The recuperation and conservation of tissues and (or) organs (parts of organs) from corpses for transplantation shall be performed in healthcare organizations in the manner determined by the authorized body.

7. The order and conditions for recuperation, collection, storage, preservation, transportation, transplantation of tissues (parts of tissue) and (or) organs (parts of organs) from donor to recipient shall be determined by the authorized body.

8. The effect of this Article shall not apply to tissues (tissue parts) and (or) organs (parts of organs) that are related to the process of human reproduction, including reproductive tissues (sex cells), as well as blood and its components.

Article 171. Rights of the donor and the recipient

1. A donor, in addition to the rights provided for in Article 165 of this Code, shall have the right to:

1) demand full information about possible complications to his health in connection with the forthcoming surgical intervention on recuperation of tissues (part of the tissue) and (or) organs (parts of organs) from the healthcare organizations;

2) receive treatment, including medicament, in the healthcare organization in connection with the surgical intervention on recuperation of tissues (tissue part) and (or) organs (parts of organs) within the guaranteed volume of free medical care.

2. A recipient shall have the right to:

1) demand full information about possible complications to his health in connection with the forthcoming surgical intervention on transplantation of tissues (part of the tissue) and (or) organs (parts of organs) from the healthcare organizations;

2) receive treatment, including medicament, in the healthcare organization in connection with the surgical intervention on recuperation of tissues (tissue part) and (or) organs (parts of organs) within the guaranteed volume of free medical care.

3. Medical and other employees of healthcare organizations shall be prohibited from disclosing information about the donor and the 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. The license to import into the territory of the Republic of Kazakhstan from countries that are not members of the Eurasian Economic Union and the export from the territory of the Republic of Kazakhstan to these countries of organs (parts of organs), human tissues in the cases provided for by subparagraph 1) of paragraph 1 and subparagraphs 1), 2) and 5) of paragraph 2 of this article shall be issued by the authorized body upon the application of healthcare organizations, carrying out activities on the specialty "transplantology", "hematology" in accordance with the license for medical activities.

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); as amended by the Law of the Republic of Kazakhstan dated 26. 12. 2017 No. 124-VI (shall be enforced from 01.01.2018).

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) the absence of components of donated blood with the necessary characteristics on the territory of the Republic of Kazakhstan;
- 2) diagnostic studies in the territory of the Republic of Kazakhstan;
- 3) joint scientific researches;
- 4) necessity to conduct laboratory studies on the NLA system to confirm the tissue compatibility of the donor living abroad and the recipient living in the Republic of Kazakhstan, as well as the immunostimulation of the recipient within the framework of hematopoietic stem cell transplantation.

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);
- 7) if it is necessary to carry out laboratory studies on the system-NLA confirming the tissue compatibility of the donor living in the Republic of Kazakhstan and the recipient living abroad, as well as the immunostimulation of the recipient within the framework of hematopoietic stem cell transplantation.

3. Is excluded by the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

4. A license on importation into the territory of the Republic of Kazakhstan from countries that are not members of the Eurasian Economic Union and export from the territory

of the Republic of Kazakhstan to these countries of blood and its components in the cases provided for by subparagraph 1) of paragraph 1 and subparagraphs 1), 2) and 5) of paragraph 2 of this article shall be issued by the authorized body upon the application of healthcare organizations, carrying out activities on the specialty "blood collection" in accordance with the license for medical activity.

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); dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 26. 12. 2017 No. 124-VI (shall be enforced from 01.01.2018); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten 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 to the territory of the Republic of Kazakhstan from countries that are not members of the Eurasian economic union, and export from the territory of the Republic of Kazakhstan to these countries of organs (parts of organs) and (or) tissues of man, blood and its components by healthcare organizations specified in paragraph 3 of article 172 and paragraph 4 of Article 173 of this Code shall be carried out on the basis of a license, issued in accordance with the procedure, established by international treaties in the field of licensing foreign trade of goods that have been ratified by the Republic of Kazakhstan and the Law of the Republic of Kazakhstan "About permits and notifications".

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); as amended by the Law of the Republic of Kazakhstan dated 16. 05. 2014 No. 203-V (shall be enforced upon expiry of six months after its first official publication); dated 26.12. 2017 No. 124-VI (shall be enforced from 01.01.2018).

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 the field of health care shall be carried out in organizations of medical and pharmaceutical education and in medical and pharmaceutical faculties of educational organizations implementing technical, vocational, post-secondary, higher, postgraduate and continuing education programs in accordance with the legislation of the Republic of Kazakhstan in the field of education. A prerequisite for the implementation of medical education programs in clinical specialties shall be the formation of university clinics and (or) integrated academic medical centers that operate on the basis of contracts with scientific and healthcare organizations.

3. State compulsory standards and standard professional training programs for medical and pharmaceutical specialties, as well as regulations on the clinical bases of education organizations in the field of healthcare and the requirements imposed on them, shall be approved by the authorized body.

4. For the persons, who have mastered the educational programs of technical and professional, post-secondary, higher, postgraduate and additional education, the basis for holding positions in medical organizations shall be the education diploma of the state sample, and for clinical specialties also the certificate of a specialist, with the exception of students of the residency.

5. Postgraduate medical and pharmaceutical education shall include residency, magistracy and doctoral studies.

6. Additional education shall be provided in medical organizations of education and science, implementing educational curricula of additional training.

The main forms of additional education shall be advanced training and retraining of medical and pharmaceutical personnel. The procedure for qualification development and retraining of medical and pharmaceutical personnel, as well as qualification requirements for organizations, implementing programs for additional medical and pharmaceutical training, shall be determined 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.

Footnote. Article 175 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 04.07.2018 № 171-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 175-1. Implementation of strategic partnership in the field of medical education and science by scientific organizations and educational organizations in the field of health care

1. Scientific organizations and organizations in the field of health care shall have the right to conclude agreements with foreign higher education institutions and (or) organizations of postgraduate education and medical organizations on strategic partnership in the field of medical education and science in order to achieve the strategic goals of sustainable development.

2. The procedure for attracting strategic partners by scientific organizations and educational organizations in the field of health care shall be determined by the authorized body.

Footnote. Chapter 29 shall be supplemented by Article 175-1 in accordance with the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 176. Certification of specialists in the field of healthcare

1. Certification of specialists in the field of healthcare shall be conducted in order to determine the readiness of individuals with secondary (technical and vocational), post-secondary, higher medical education, as well as persons, who have been retrained and (or) acquired postgraduate education, to carry out medical activities and admit them to clinical practice (work with patients) with the issuance of a specialist certificate.

Certification of specialists in the field of healthcare shall be carried out on the basis of an assessment of professional preparedness, confirmation of the conformity of specialists' qualifications in the field of healthcare, conducted by organizations, that assess professional preparedness and confirm the conformity of specialists' qualifications in the field of healthcare, accredited by the authorized body in the manner, determined by the authorized body.

2. An individual without an appropriate specialist's certificate shall be forbidden to engage in clinical practice, with the exception of residency students, who are admitted to clinical practice (working with patients) under the supervision of a specialist, having the appropriate certificate.

Deprivation of the certificate of a specialist in the field of healthcare shall be carried out in accordance with the Code of the Republic of Kazakhstan on administrative offenses.

3. The procedure and terms for certification of specialists in the field of healthcare, as well as the procedure for assessing professional preparedness and confirming the conformity of specialists' qualifications in the field of healthcare shall be determined by the authorized body.

4. The procedure and conditions for admission to certification of specialists in the field of healthcare of persons, having received medical education outside the Republic of Kazakhstan shall be determined by the authorized body.

5. A document, giving the right to engage in medical activities or certifying the assignment of a qualification category obtained by foreign specialists abroad, invited in

accordance with the legislation of the Republic of Kazakhstan to carry out medical activities, shall be equivalent to a specialist's certificate.

Footnote. Article 176 is in the wording of the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of six months after its first official publication).

Article 176-1. Assignment and withdrawal of qualification categories

1. The assignment of qualification category shall be a voluntary procedure, conducted to determine the level of qualification of specialists with medical and pharmaceutical education, with the assignment of the appropriate qualification category, with the issuance of a certificate of qualification for a particular specialty.

The assignment of the qualification category shall be carried out on the basis of an assessment of professional preparedness and confirmation of the conformity of specialists' qualification in the field of healthcare, organizations, that perform assessment of professional preparedness and confirmation of the compliance of specialists' qualifications in the field of healthcare, accredited by the authorized body in the manner, determined by the authorized body.

2. In the presence of a certificate of assignment of a qualification category, issued by an authorized body, a specialist in the field of healthcare shall have the right to obtain a certificate of a specialist.

3. The list of qualification categories shall be approved by the authorized body.

4. The procedure, terms of issue and withdrawal of the certificate of a qualification category for the specialists in the field of healthcare, with the exception of specialists in the field of sanitary and epidemiological welfare of the population, shall be determined by the authorized body.

5. The procedure, terms of issue and withdrawal of the certificate of assignment of a qualification category for the specialists in the field of sanitary and epidemiological welfare of the population shall be determined by the state body in the field of sanitary and epidemiological welfare of population.

Footnote. Chapter 29 is supplemented by Article 176-1 in accordance with the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of six months 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. Conduct of medical research

1. Medical research can be conducted on living people and animals (research subjects), biological samples of living and deceased people and animals, as well as based on the use of clinical and epidemiological data and other medical information.

Medical research shall include biomedical experiments, preclinical (non-clinical) research, clinical research and public health research.

2. Creation of human embryos for medical research purposes and the cloning of humans shall be prohibited.

3. Medical research of human embryos or human fetuses during which or after which a human embryo or human embryo is destroyed shall be prohibited.

4. Medical research can be carried out only in simultaneous compliance with the following requirements:

1) medical research is aimed at obtaining new scientific data and their introduction into practical health care;

2) the interests of the subject of the research and the confidentiality of his medical information are protected;

3) the consent of the subject of research or his legal representative to participate in the research or use of his biological samples and medical information, including to fill the biobank for scientific purposes, is received;

4) interventional clinical researches are conducted with the permission of the authorized body.

5. For the following categories of persons, medical research shall be carried out only in the case when it cannot be conducted on other persons and there are scientific grounds to expect that participation in such medical research will bring them direct benefit, outweighing the risks and inconveniences, associated with medical research:

1) minors;

2) pregnant women;

3) incapacitated;

4) students in the cases where participation in medical research is related to their studies;

5) retired persons in need of assistance;

6) military personnel;

7) staff of medical organizations where medical research is conducted;

8) persons held in the penitentiary institutions.

6. When obtaining consent to participate in a medical research, the legal representative of a minor, the guardian of an incapacitated person, a patient or a volunteer must be provided with the information:

1) on medical technology, pharmacological or medicinal product, the nature and duration of the medical research;

2) on the degree of safety, the risks and the expected effectiveness of the medical technology, pharmacological or medicinal product;

3) on actions in case of unforeseen effects of application of medical technology, pharmacological or medicinal product on the state of health;

4) on health insurance conditions.

In this case, before the start of medical research, the legal representative of a minor, the guardian of an incapacitated person, a patient or a volunteer should be informed about the possibility of rejecting medical research at any stage of the study.

7. Medical research shall be terminated at any stage:

1) at the request of a minor participating in the research, his legal representative, guardian of an incapacitated person, patient or volunteer;

2) in the event of a threat to the life or health of a minor, an incapacitated person, a patient or a volunteer.

8. Obligatory conditions for conducting medical research shall be the execution of documents on insurance of life and health of the research participants and the positive conclusion of the commission on bioethics.

9. Rules for conducting medical research and requirements for research centers shall be approved by the authorized body.

Footnote. Article 180 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

Article 181. Commission on bioethics

1. The Commission on bioethics shall be an independent expert body, conducting bioethical examination of documents, related to conducting medical research at the planning stage, during and after completion in order to ensure the safety and protection of the rights of participants of medical research.

2. In the Republic of Kazakhstan, the Central Commission on bioethics and local commissions on bioethics shall work.

3. The Central Commission on bioethics shall be established under an authorized body to perform the following tasks:

1) analysis and information of specialists and the public on bioethics in the context of development of modern health care;

2) issuance of opinions for conducting interventional clinical research of medicines and medical devices of foreign production, as well as interventional clinical research of medicines and medical products, conducted in two or more research centers, located in the Republic of Kazakhstan;

3) bioethical monitoring of the progress of medical research for which the opinion was issued by the Central Commission for bioethics and the permission of the authorized body;

4) coordination of the activities of local commissions on bioethics and assessment of their compliance with the standards, approved by the Central Commission on bioethics;

5) participation in development of documents on bioethics.

4. Central and local commissions on bioethics shall be formed on an interdisciplinary basis and consist of representatives of medical and humanitarian professions, public organizations and specialists in the field of law.

5. The composition and regulations of the Central Commission on bioethics shall be approved by the authorized body.

6. Local commissions on bioethics shall be established at medical organizations to perform the following tasks:

1) issuance of opinions for conducting medical research, except for the cases specified in subparagraph 2) of paragraph 3 of this article;

2) bioethical monitoring of the progress of medical research for which the opinion of this local commission on bioethics and the permission of the authorized body are issued;

3) submission of the annual report to the Central Commission on bioethics in the order, determined by it.

7. The composition and regulations of the local commission on bioethics shall be approved by the order of the first head of the medical organization, where the commission is established, in coordination with the Central Commission on bioethics.

8. Local commissions on bioethics shall have the right to issue opinions for conducting medical research, subject to the availability of a certificate of compliance with the standards of commissions on bioethics, issued by the Central Commission on bioethics.

9. The validity period of the certificate of compliance with the requirements of the activities of commissions on bioethics and the procedure for its issuance shall be determined by the Central Commission on bioethics.

Footnote. Article 181 shall be in the wording of the Law of the Republic of Kazakhstan dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication).

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) professional liability insurance for causing harm to the life or health of the patient in the absence of negligent treatment by a medical specialist.

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) payment of utilities and procurement of fuel at the expense of budget funds in the manner and amount, approved by local representative bodies;

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 workers whose work duties can lead to occupational HIV disease shall be subject to compulsory social insurance.

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;

5-1) immediately report to law enforcement authorities about the facts of actions (inaction), performed by minors or in relation to them, containing signs of a criminal or administrative offense in health care organizations, as well as facts that became known to them in connection with their professional activities outside of health care organizations;

6) continuously develop and improve their professional level, including by continuing to improve their qualifications every five years;

6-1. Medical workers shall be subject to obligatory assessment of professional preparedness and confirmation of compliance of specialists' qualification in the field of healthcare.

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.); dated 06.04.2015 № 299-V (shall be enforced upon expiry of ten calendar days after its first official publication); dated 02.07.2018 No. 165-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 28.12.2018 No. 208-VI (shall be enforced upon expiry of ten calendar days after its first official publication); dated 01.04.2019 No. 240-VI (shall be enforced upon expiry 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;
- 7) explain the principles of joint responsibility for the protection of one's own health.

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.

Footnote. Article 184 as amended by the Law of the Republic of Kazakhstan dated 06.04.2015 No. 299-V (shall be enforced upon expiry of ten calendar days after its first official publication).

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 of 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 visit organizations 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 shall coordinate 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 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) suspected or accused of committing a criminal offense; 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. Persons, who are exempted from criminal liability under articles 3, 4, 9, 10 and 12 of part one of Article 35 or Article 36 of the Code of Criminal procedure of the Republic of Kazakhstan for committing an intentional crime cannot also participate in the national preventive mechanism; dismissed from the state or military service, from law enforcement and special state bodies, courts or excluded from the bar of advocates for negative reasons; deprived of a license to practice as a lawyer.

Footnote. Article 184-3 as amended by the Law of the Republic of Kazakhstan dated 04.07.2014 No. 233-V (shall be enforced from 01.01.2015).

Article 184-4. Rights of a participant of the national preventive mechanism

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.

Article 184-5. 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 the Laws 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 make 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 185-1. Transitional Provisions

Footnote. Chapter 32 is supplemented with Article 185-1 in accordance with the Law of the Republic of Kazakhstan dated 16.11.2015 No. 406-V (shall be enforced from 01.01.2016) ; excluded by Law of the Republic of Kazakhstan No. 208-VI dated 28.12.2018 (shall be enforced since 01.01.2020).

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 be enforced upon 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; No 10, Art. 69; No 19, Art. 147; No 20, 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