



## ON PUBLIC HEALTH AND HEALTHCARE SYSTEM

### *Unofficial translation*

Code of the Republic of Kazakhstan dated July 7, 2020 No. 360-VI 3PK.

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Throughout the whole text, words “preventive control and supervision” were prescribed to replace by words “preventive control” in accordance with the Law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.01.2023).

## SECTION 1. GENERAL PROVISIONS

### Chapter 1. PRINCIPAL PROVISIONS

#### Article 1. Basic concepts used in this Code

1. The following basic concepts are used in this Code:

- 1) human habitat (hereinafter - the habitat) - a set of natural, anthropogenic and social environmental factors (natural and artificial) that determine the conditions of human life;
- 2) HIV infection - a chronic infectious disease caused by the human immunodeficiency virus, characterized by a specific damage to the immune system and leading to its slow destruction until the formation of acquired immunodeficiency syndrome;
- 3) a certified first aid trainer - a person who has passed additional training in first aid and basic cardiopulmonary resuscitation;
- 4) anonymous examination - voluntary medical examination of a person without personal identification;
- 5) disaster medicine - the field of medicine aimed at preventing and eliminating the medical and sanitary consequences of emergencies of a social, natural and man-made nature (hereinafter - emergencies), including the prevention and treatment of diseases of the population, sanitary-anti-epidemic and sanitary-preventive measures, preservation and restoration of health of participants in the liquidation of emergency situations, as well as medical assistance to employees of emergency services;
- 6) social health insurance fund - a non-profit organization that accumulates allocations and contributions, as well as purchases and pays for the services of healthcare entities providing medical care in the volumes and on the terms provided for by the contract for the purchase of healthcare services, and other functions determined by the laws of the Republic of Kazakhstan;
- 7) military medicine is the field of medicine and healthcare, which is a system of scientific knowledge (a complex of scientific and practical disciplines) and practical activities

of the military medical service, which has as its goal the comprehensive medical support of troops, units and departments of special state and law enforcement agencies in peaceful and military time;

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

9) military-medical (medical) subdivisions - structural subdivisions of the central executive bodies and other central state bodies and their territorial subdivisions, as well as military-medical (medical) institutions (organizations), other subdivisions providing military-medical (medical) support;

10) enrichment (fortification) - the introduction of vitamins, minerals and other substances into food products in the course of their production or processing in order to increase the nutritional and biological value, as well as to prevent diseases caused by their deficiency in humans;

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

12) specialized professional - a medical worker with a diploma of higher medical education who has a certificate in the field of healthcare;

13) established (final) sanitary protection zone - the territory of the sanitary protection zone, determined on the basis of the results of the annual cycle of field studies and measurements to confirm the calculated (preliminary) sanitary protection zone;

14) a list of pharmaceuticals and medical devices for free and (or) preferential outpatient provision of certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions) - a list of pharmaceuticals, medical devices and specialized medical products purchased at the expense of budget funds and (or) assets fund of social health insurance within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance in the provision of primary healthcare and specialized medical care on an outpatient basis, including the names and characteristics of drugs, medical devices and specialized medical products in the context of certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions);

15) similar biological medicinal product (biosimilar, follow-on biologic, biosimilar) - a biological medicinal product, which contains a version of the active ingredient of the registered biological original medicinal product or the reference product and which demonstrated similarity (likeness) on the basis of comparative studies on the quality indicators, biological activity, safety and efficiency;

16) biobank - a specialized storage of biological materials for scientific and medical purposes;

17) biologically active substances - substances of natural origin or their synthetic analogs that normalize pathologically altered body functions in animals and humans;

18) biological medicinal product - 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 it is necessary to combine biological and physicochemical methods of analysis with an assessment of the production process and methods of its control;

19) medicinal products of biological origin - preparations containing biological substances (hormones, cytokines, blood coagulation factors, insulins, monoclonal antibodies, enzymes, colony-stimulating factors, preparations based on tissue cells, and others obtained using biotechnological methods);

20) biomedical research - research, the purpose of which is to obtain by scientific methods new knowledge about life, human health, diseases, their diagnosis, treatment or prevention, as well as genetic and environmental factors associated with life processes, diseases and health;

21) biotechnological medicinal product - a medicinal product produced using biotechnological processes and application of methods using recombinant deoxyribonucleic acid technology, controlled expression of genes encoding the production of biologically active proteins, hybridoma technologies, monoclonal antibodies or other biotechnological processes;

22) bioethics - an interdisciplinary scientific direction that combines biomedical and humanitarian sciences in order to analyze the moral, social, legal aspects of the application of the latest achievements of the life sciences;

23) childbirth - natural or artificial (instrumental, manual, medication) completion of the accouchement;

24) the maximum price for the trade name of a medicine for retail sale – - the price for the trade name of a medicine, included into the list of medicines that are subject to price regulation, above which its retail sale cannot be carried out;

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

26) co-payment - payment of the difference in the cost of pharmaceuticals, medical devices and the established maximum price for their reimbursement within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance at the outpatient level, carried out on a voluntary basis;

27) a single distributor - a legal entity operating within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance in accordance with Article 247 of this Code;

28) vaccines - medicinal products for specific prophylaxis of infectious diseases, providing a preventive effect through the immune system;

29) hematopoietic stem cells - hematopoietic cells of the human bone marrow that have pluripotency and are in the process of life in the bone marrow, peripheral blood and umbilical cord blood;

30) register of donors of hematopoietic stem cells (bone marrow) - a list of persons agreeing to donation of hematopoietic stem cells (bone marrow) and typed according to the HLA system;

31) genetically modified objects - raw materials and products of plant and (or) animal origin obtained using methods of genetic engineering, including genetically modified sources, organisms;

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

33) pharmaceutical product - a product that is or contains a substance or a combination of substances that comes into contact with the human body, intended for the treatment, prevention of human diseases or recovery, correction or change of its physiological functions through pharmacological, immunological or metabolic effects, or for diagnostics diseases and human conditions;

34) marginal price for a pharmaceutical product - a price above which the sale of a pharmaceutical product cannot be carried out;

35) circulation of pharmaceuticals - activities that include development processes, preclinical (non-clinical) studies, trials, clinical trials, expertise, registration, pharmacovigilance, quality control, production, manufacturing, storage, transportation, import and export, release, sale, transfer, use, destruction of pharmaceuticals;

36) good pharmaceutical practices in the field of drug circulation (hereinafter referred to as good pharmaceutical practices) - health standards that apply to all stages of the life cycle of drugs: 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 Good Pharmaceutical Practices;

37) the manufacturer of pharmaceuticals - an organization engaged in the production of pharmaceuticals and having a license to manufacture pharmaceuticals;

38) the register of authorized persons of drug manufacturers - an electronic information resource of the authorized body containing information on authorized persons of drug manufacturers;

39) an authorized person of a manufacturer of pharmaceuticals - a person responsible for ensuring and controlling the quality of pharmaceuticals produced by the manufacturer in accordance with the legislation of the Republic of Kazakhstan in the field of healthcare, and included in the register of authorized persons of manufacturers of pharmaceuticals;

40) rational use of pharmaceuticals - drug treatment that meets clinical indications, in doses that meet the individual needs of the patient for a sufficient period of time and at the lowest cost;

41) long-term contract for the supply of medicines and medical products – a civil contract concluded by a single distributor for up to ten years with the right to extend up to three years with a manufacturer of medicines or medical products located on the territory of the Republic of Kazakhstan or with a customer for the contract production of original patented medicines, as well as with customers of the contract production of medical products for the supply of medicines or medical products or with a subject in the field of circulation of medicines and medical products, having the intention to establish production or modernize the existing production of medicines and medical products located on the territory of the Republic of Kazakhstan, in accordance with the procedure established by the legislation of the Republic of Kazakhstan;

42) retail sale of pharmaceuticals and medical devices - pharmaceutical activities related to the acquisition (except for import), storage, distribution, sale (except for export) to the end consumer, destruction of pharmaceuticals and medical devices;

43) contract manufacturing of pharmaceuticals and medical devices (hereinafter - contract manufacturing) - the production of pharmaceuticals and medical devices on a contract basis at the production facilities of manufacturers of pharmaceuticals and medical devices located in the Republic of Kazakhstan, which ensure full compliance with the requirements of good manufacturing practice (GMP) for pharmaceuticals and the international quality management system standard (ISO 13485) for manufacturers of medical devices;

44) web portal for the procurement of pharmaceuticals and medical devices, services from healthcare entities - an information system that provides a single point of access to electronic services for the purchase of pharmaceuticals and medical devices, services from healthcare entities within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

45) a single operator in the field of procurement of pharmaceuticals and medical devices, services from healthcare entities (hereinafter - a single operator) - a legal entity determined by the authorized body in agreement with the authorized body in the field of public procurement;

46) wholesale of pharmaceuticals and medical devices - pharmaceutical activities related to the purchase (acquisition), storage, import, export, sale (except for the sale to the population) without limiting the volume, transportation and destruction of pharmaceuticals and medical devices;

47) a state body in the field of circulation of pharmaceuticals and medical devices - a state body that exercises leadership in the field of circulation of pharmaceuticals and medical devices, control over the circulation of pharmaceuticals and medical devices;

48) a state expert organization in the field of circulation of pharmaceuticals and medical devices - a state monopoly entity carrying out production and economic activities in the field

of public health to ensure the safety, efficiency and quality of pharmaceuticals and medical devices;

49) objects in the field of circulation of medicines and medical products – pharmacy, including those selling via the Internet, pharmacy in healthcare organizations and mobile pharmacy for rural settlements, pharmacy (distribution) warehouse, temporary storage warehouse of medicines, medical products, optics store, medical products store, medical products warehouse, organizations for production of medicines and medical products;

50) entities in the field of circulation of pharmaceuticals and medical devices - individuals or legal entities engaged in pharmaceutical activities;

51) The State Register of Pharmaceuticals and Medical Devices is an electronic information resource containing information on pharmaceuticals and medical devices registered and permitted for medical use in the Republic of Kazakhstan;

52) a long-term contract for the storage and transportation of pharmaceuticals and medical devices - a civil law contract for the provision of services, concluded by a single distributor with an entity in the field of circulation of pharmaceuticals and medical devices - a resident of the Republic of Kazakhstan, which meets the requirements of good distribution practice (GDP);

53) state re-registration of a pharmaceutical product or medical device - the procedure for extending the validity period of state registration of a pharmaceutical or medical device with the issuance of an unlimited document certifying state registration (hereinafter - registration certificate), under the previous registration number and making a corresponding entry in the State Register of Pharmaceuticals and Medical Devices;

54) state registration of a pharmaceutical product or medical device - the procedure for obtaining permission to circulate pharmaceuticals or medical devices in the territory of the Republic of Kazakhstan and entering a pharmaceutical product or medical device for a specified period in the State Register of Pharmaceuticals and Medical Devices;

55) shelf life of a pharmaceutical product - the date after which the pharmaceutical product is not subject to use;

56) packaging of a pharmaceutical product - a product or a set of products that ensure the process of circulation of pharmaceuticals by protecting them from damage and loss, as well as protecting the environment from pollution;

57) bulk - a product of a pharmaceutical product or medical device - a dosed finished drug or a finished medical device that has passed all stages of the technological process, except for the final packaging;

58) making changes to the registration dossier of a pharmaceutical product or medical device - a procedure carried out on the basis of an examination of the changes made to the registration dossier during the validity of the registration certificate;

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

60) regulatory document on the quality of a pharmaceutical product - a document that establishes requirements for quality control of a pharmaceutical product in the post-registration period on the basis of an expert examination of a pharmaceutical product during its registration and contains a specification, a description of analytical methods and tests of a pharmaceutical product or references to such tests, as well as relevant acceptance criteria for quality indicators;

61) trade name of a pharmaceutical product - the name under which the pharmaceutical product is registered;

62) international non-proprietary name of a pharmaceutical product - the name of a pharmaceutical product recommended by the World Health Organization;

63) quality of drug supply - the level of compliance with the requirements of healthcare standards governing the production, import, storage, timely delivery of drugs and pharmacovigilance;

64) dosage formulation - the state of a pharmaceutical product corresponding to the methods of its administration, use and ensuring the achievement of the required therapeutic effect;

65) medicinal plant raw materials - fresh or dried plants, algae, mushrooms or lichens or parts thereof, whole or crushed, used for the production of pharmaceuticals;

66) pharmaceutical product - a pharmaceutical product in the form of a dosage formulation;

67) manufacturing of pharmaceutical products - pharmaceutical activities related to the manufacture of pharmaceutical products in pharmacies, the purchase of pharmaceutical substances (active pharmaceutical ingredients) for pharmaceutical use, storage, quality control, registration and sale of manufactured pharmaceutical products;

68) safety of a pharmaceutical product - the absence of an unacceptable risk when using a pharmaceutical product associated with the possibility of harming life, human health and the environment;

69) efficacy of a pharmaceutical product - a set of characteristics of a pharmaceutical product that ensure the achievement of a prophylactic, diagnostic or therapeutic effect or restoration, correction or modification of physiological function;

70) medicinal raw materials - substances of plant, mineral, animal origin or products of the chemical industry used for the production and manufacture of pharmaceuticals;

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

72) disinfection - a set of special measures aimed at destroying pathogens of infectious and parasitic diseases in the external environment;

73) health - a state of complete physical, spiritual (mental) and social well-being, and not just the absence of diseases and physical defects;

74) healthcare - a system of measures of a political, economic, legal, social, cultural, medical nature aimed at preventing and treating diseases, maintaining public hygiene and sanitation, maintaining and strengthening the physical and mental health of each person, maintaining his/her active long-term life, providing him/her medical assistance in case of loss of health;

75) healthcare system - a set of state bodies and healthcare entities the activities of which are aimed at ensuring the rights of citizens of the Republic of Kazakhstan to health protection;

76) regional long-term plan for the development of healthcare infrastructure - a long-term plan for the development of the infrastructure of the region, reflecting information on the existing network of healthcare organizations, planned restructuring (opening, merging, closing, re-orientation), as well as information on the need for new healthcare facilities and investment planning;

77) certification of scientific and pedagogical personnel of educational organizations in the field of public health - the procedure for determining the level of pedagogical and professional competence of scientific and pedagogical personnel of educational organizations in the field of healthcare;

78) organization of education in the field of public health - an organization of education that implements educational programs in the areas of training "Healthcare" and (or) "Interdisciplinary Programs Related to Healthcare and Social Security (Medicine)";

79) clinic of educational organization in the field of public health - a structural subdivision of an educational organization or a healthcare organization, on the basis of which educational programs of technical and professional, post-secondary, higher, postgraduate and additional medical education are implemented on the basis of modern achievements of science and practice;

80) scientific organization in the field of public health - a national center, scientific center or research institute carrying out scientific, scientific and technical and innovative activities in the field of healthcare, as well as medical, pharmaceutical and (or) educational activities;

81) professional standard in the field of public health - a standard that determines the requirements for the level of qualifications, content, quality and working conditions of specialists in the field of healthcare;

82) certification of a healthcare specialist - a procedure for determining the compliance of an individual's qualifications with the qualification requirements established by the industry qualifications framework and professional standards in healthcare, as well as determining the readiness for professional activities in the healthcare sector, including readiness for clinical or pharmaceutical practice, or activities in the sphere of sanitary and epidemiological welfare of the population;



83) certificate of a healthcare specialist - a document of the established form confirming the qualifications of an individual and his/her readiness for professional activities in the field of healthcare, including readiness for clinical or pharmaceutical practice, or activities in the field of sanitary and epidemiological well-being of the population;

84) manager in the field of public health - the first head who manages a state medical organization;

85) certificate of a healthcare manager - a document of the established form for engaging in activities for the management of a state medical organization;

86) examination in the field of public health - a set of organizational, analytical and practical measures aimed at determining the effectiveness and quality of means, methods, technologies, educational and scientific programs, services in various areas of healthcare, as well as determining temporary disability, professional fitness for health reasons in accordance with the legislation of the Republic of Kazakhstan;

87) standard in the field of public health (hereinafter referred to as the standard) - a regulatory legal act that establishes the rules, general principles and characteristics to ensure standardization in the field of public health in the field of medical, pharmaceutical activities, educational and scientific activities in the field of healthcare, digital healthcare;

88) standardization in the field of public health (hereinafter - standardization) - activities aimed at achieving the optimal degree of streamlining the characteristics of processes, technologies and healthcare services through the development, implementation and enforcement of standards, requirements, norms, instructions, rules;

89) an authorized body in the field of public health (hereinafter referred to as an authorized body) is a central executive body that carries out management and inter-sectoral coordination in the field of health protection of citizens of the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological well-being of the population, circulation of pharmaceuticals and medical devices, the quality of healthcare services (assistance);

90) national operator in the field of public health - a legal entity carrying out activities in the field of healthcare, including the development of healthcare infrastructure;

91) health technology assessment - a comprehensive assessment of the comparative proven clinical and clinical and economic (pharmacoeconomic) effectiveness and safety of health technologies, as well as the economic, social and ethical consequences of their use, carried out for decision-making in the field of healthcare;

92) healthcare technology - the application of knowledge and skills that are used to promote health, prevention, diagnosis, treatment of illness, rehabilitation of patients and the provision of palliative care, including vaccines, drugs and medical devices, procedures, manipulations, operations, screening, preventive programs, including information systems;

93) healthcare organization - a legal entity carrying out activities in the field of healthcare;

94) pharmaceutical formulary of a healthcare organization - a list of pharmaceuticals for the provision of medical care within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance, formed on the basis of the Kazakhstan National Drug Formulary and approved by the head of the healthcare organization in the manner determined by the authorized body;

95) joint responsibility for health - the division of responsibility between the members of society: the state, the employer and the citizen himself for the preservation and strengthening of individual and public health, reducing the risk of disease;

96) deratization - a set of preventive and exterminatory measures aimed at destroying or reducing the number of rodents;

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

98) diagnostics - a set of healthcare services aimed at establishing the presence or absence of a disease;

99) dynamic observation - systematic observation of the patient's health, as well as the provision of the necessary medical care based on the results of this observation;

100) donor - a person, a human corpse, an animal from which donor blood, its components, other donor material (including sperm, eggs, tissue of reproductive organs, reproductive cells, embryos), as well as the removal of organs (parts of an organ) and/or tissues (parts of tissue) for transplantation to a recipient;

101) donor organization - a healthcare organization in which the removal and conservation of organs (parts of an organ) and (or) tissues (parts of tissue) from corpses is carried out for the purpose of transplantation;

102) donor function - the donor's voluntary medical examination and allogeneic donation of blood and its components;

103) treatment - a complex of healthcare services aimed at eliminating, stopping and (or) alleviating the course of the disease, as well as preventing its progression;

104) attending physician - a doctor who provides medical care to a patient during the period of his/her observation and treatment in a medical organization;

105) voluntary treatment - treatment carried out with the consent of the patient or his/her legal representative;

106) calculated (preliminary) sanitary protection zone - the territory of the sanitary protection zone, determined on the basis of the project with calculations of dispersion of atmospheric air pollution, physical (noise, vibration, non-ionizing radiation) and (or) radiation effects on human health;

107) undesirable reaction - an unintentional, adverse reaction of the body associated with the use of a medicinal (investigational) drug and suggesting the presence of a possible relationship with the use of this medicinal (investigational) drug;

108) counterfeit pharmaceuticals and medical devices - pharmaceuticals, medical devices, unlawfully and intentionally supplied with false information about their composition or configuration and (or) manufacturer, as well as about supplies, including records and documents concerning the used supply channels;

109) personal medical record - a personal document in which the results of mandatory medical examinations are entered with a mark on admission to work;

110) high-tech medical service - a service provided by specialized professionals for diseases requiring the use of innovative, resource-intensive and (or) unique methods of diagnosis and treatment;

111) artificial termination of pregnancy - termination of pregnancy prior to the term of fetal viability using medication or surgical methods, carried out by medical workers with higher medical education in the relevant profile;

112) mobile medical complexes - mobile clinics (offices) based on road transport, equipped with the necessary medical equipment, which are used to ensure the availability and expansion of the list of healthcare services provided to the population of rural areas and remote settlements or in the interests of defence and national security;

113) sexually transmitted infections - infectious diseases, the most frequent route of infection of which is sexual contact;

114) person with gender identity disorders - a person seeking to live and be accepted as a person of the opposite sex;

115) immunological pharmaceutical product (immunobiological medicinal product) - a medicinal product intended for the formation of active or passive immunity or diagnosis of the presence of immunity, or diagnosis (development) of a specific acquired change in the immunological response to allergenic substances;

116) system of immunological typing (hereinafter referred to as the HLA system) - a system of antigens located on human leukocytes and determining the tissue compatibility of the donor and recipient during organ (part of an organ) and (or) tissue (part of tissue) transplantation;

117) invasive methods - methods of diagnosis and treatment, carried out by penetration into the internal environment of the human body;

118) innovative medical technologies - a set of methods and means of scientific and scientific and technical activities, the implementation of which in the field of medicine (biomedicine), pharmacy and digitalization of healthcare is socially significant and (or) cost effective;

119) an integrated academic medical center - an association of an organization of higher and (or) postgraduate medical education with scientific organizations in the field of public health and health organizations in order to share resources to improve the quality of healthcare services through the integration of education, research and clinical practice;

120) non-interventional clinical research - a research that is carried out after the state registration of a pharmaceutical product or medical device and is assigned within the framework of medical practice;

121) interventional research - a research involving a human being as a clinical trial participant, in which a research doctor, on the basis of an interventional clinical research protocol, corresponding to the procedure for conducting clinical research, prescribes a special intervention to the clinical trial participant;

122) epidemiological surveillance of non-communicable diseases - the activities of state bodies and organizations of the sanitary and epidemiological service to monitor risk factors from the impact of environmental objects affecting the health of the population, including production factors, occupational diseases with temporary disability, minimization and control over the implementation chronic noncommunicable disease management programs;

123) infectious and parasitic diseases - human diseases, the appearance and spread of which are caused by the impact of biological factors of the environment on humans and the possibility of transmission of the disease from a sick person, animal to a healthy person;

124) iodine deficiency disease - a pathological process of the body caused by dysfunction of the thyroid gland associated with insufficient intake and assimilation of iodine in the body;

125) occupational disease - an acute or chronic disease caused by exposure of an employee to harmful production factors in connection with the performance of his/her labor (official) duties;

126) biological material of preclinical (nonclinical) and clinical studies - samples of biological fluids, tissues, secretions and waste products of humans and animals, biopsy material, histological sections, smears, scrapings, swabs obtained during preclinical (nonclinical) and clinical studies and intended for laboratory research;

127) preclinical (nonclinical) research - chemical, physical, biological, microbiological, pharmacological, toxicological and other experimental research or a series of studies to study an investigated substance (drug) by applying scientific assessment methods in order to study a specific action and (or) obtain evidence safety for human health;

128) clinical base - a healthcare organization, which is used by an educational organization for training and advanced training of personnel in the field of public health under an agreement on joint activities;

129) clinical research - a study with human participation as a clinical trial participant, conducted to identify or confirm the safety and efficacy of means, methods and technologies for the prevention, diagnosis and treatment of diseases;

130) clinical nursing guidance - a document containing scientifically proven recommendations for nursing personnel on patient care, suggesting the use of preventive, diagnostic, therapeutic and rehabilitation measures in the management of patients;

131) clinical pharmacologist - a specialist with higher medical education in the field of “General Medicine”, “Pediatrics”, “General Medicine”, who has mastered the program of

residency or retraining in clinical pharmacology and has a certificate of a healthcare specialist ;

132) clinical protocol - scientifically proven recommendations for the prevention, diagnosis, treatment, medical rehabilitation and palliative care for a specific disease or condition of the patient;

133) concilium - a medical examination of a person in order to establish a diagnosis, determine treatment tactics and prognosis of a disease with the participation of at least three doctors;

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

135) the maximum price for a trade name of a medicine for wholesale – the price for the trade name of a medicine, included into the list of medicines that are subject to price regulation, above which its wholesale cannot be carried out;

136) Kazakhstan National Drug Formulary - a list of pharmaceuticals with proven clinical safety and efficacy, as well as orphan (rare) medicinal products, which is a mandatory basis for the development of medicinal formularies of medical organizations and the formation of lists for the purchase of pharmaceuticals within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

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

138) State Pharmacopoeia of the Republic of Kazakhstan - a set of minimum requirements for the safety and quality of pharmaceuticals and medical devices;

139) the register of pharmaceutical inspectors of the Republic of Kazakhstan - an electronic information resource of the authorized body containing information about pharmaceutical inspectors of the Republic of Kazakhstan;

140) a generic medicinal product (generic) is a medicinal product that has the same quantitative and qualitative composition of active ingredients and the same dosage form as the original medicinal product, and the bioequivalence of which to the original medicinal product is confirmed by appropriate bioavailability studies. Various salts, esters, isomers, mixtures of isomers, complexes or derivatives of an active ingredient are recognized as the same active ingredient if their safety and efficacy do not differ significantly. Different immediate-release oral dosage forms are recognized in bioavailability studies for the same dosage form;

141) allogeneic donation of blood and its components - donation of blood and its components for medical use from one person to another;

142) pre-exposure prophylaxis - antiretroviral therapy applied to uninfected people to prevent HIV infection;

143) post-exposure prophylaxis - antiretroviral therapy used to reduce the risk of contracting HIV infection after a possible infection;

144) public health - a comprehensive characteristic of the mental, physical and social well-being of the population, reflecting the efforts of society to maintain a healthy lifestyle by the citizens of the Republic of Kazakhstan, including healthy eating, to prevent diseases and injuries, as well as to prevent the influence of adverse environmental factors;

145) research in the field of public health - a study conducted on the basis of the collection and generalization of clinical and epidemiological data and other medical information to identify the main factors that affect health and determine the development of the healthcare system, develop methods of targeted influence and management of these factors;

146) adverse event - any malfunction and (or) deterioration in the performance or malfunction of a medical device, or inadequacy or inaccuracy of accompanying information (documentation) for a medical device, side effects or an unwanted reaction not specified in the instructions for use or operating instructions, which directly or indirectly led or could lead to the death or serious deterioration of the health of users or third parties;

147) applied biomedical research - biomedical research aimed at achieving specific goals in the field of diagnosis, treatment or prevention of diseases, ensuring public health;

148) hookah - a device used for inhalation of aerosol, vapor or smoke arising from smoldering and (or) heating of tobacco, as well as products that do not contain tobacco leaves, and in which aerosol, vapor or smoke passes through a vessel with liquid;

149) hookah tobacco - a type of smoking tobacco product intended for smoking using a hookah and consisting of a mixture of cut or torn raw materials with or without the addition of non-tobacco raw materials and other ingredients;

150) hookah mix - a product made without using tobacco leaf as a raw material, prepared in such a way as to be used for consumption using a hookah;

151) excipient - a substance, with the exception of pharmaceutical substances (active pharmaceutical ingredients), which is a part of a medicinal product to give it the necessary properties;

152) confidential medical examination - examination based on the observance of the secrecy of the medical worker and the preservation of information on the identity of the examined person;

153) compulsory medical treatment - treatment of a patient, carried out on the basis of a court decision;

154) medical worker - an individual with a professional medical education carrying out medical activities;

155) medical aviation - the provision of emergency medical care to the population with the involvement of air transport;

156) medical information - information about patients and diseases arising in the process of providing medical care and reflected in medical documents and medical information systems, as well as information on health issues;

157) medical intervention - direct or indirect impact and (or) other manipulation performed by a medical worker in the provision of medical care to patients for the purpose of prevention, prophylaxis, diagnosis, treatment, rehabilitation, research and aimed at restoring or improving health;

158) medical and social assistance is medical and social and psychological assistance provided to persons with socially significant diseases, the list of which is determined by the authorized body;

159) medical and social rehabilitation – a set of measures to restore the health of patients and persons with disabilities using medical, social and professional-labor measures for introduction to work, inclusion in family and social life;

160) biomedical experiment – a study based on the reproduction (modeling) of the structural and functional complex of the studied condition or disease in a simplified form on experimental (laboratory) animals to clarify the causes, conditions and mechanisms of the onset of the condition or development of the disease, the development of methods of treatment and prevention;

161) medical devices - medical devices and medical equipment;

162) consumables for medical devices - products and materials consumed when using medical devices, ensuring manipulations in accordance with the functional purpose of the medical device, operational characteristics, the manufacturer's service manual;

163) circulation of medical devices - design, development, creation of prototypes, technical testing, research (testing) assessment of the biological effect of medical devices, clinical studies, examination of the safety, quality and effectiveness of medical devices, registration, production (manufacturing), storage, transportation, implementation, installation, adjustment, application (operation), maintenance, repair and disposal of medical devices;

164) studies (tests) for assessing the biological effect of medical devices - studies (tests) conducted in order to determine the compliance of medical devices with the general requirements for the safety and effectiveness of medical devices, the requirements for their labeling and operational documentation for them;

165) Global Medical Device Nomenclature (GMDN) - a systematized nomenclature classifier of types of medical devices used to identify medical devices;

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

167) monitoring of the safety, quality and effectiveness of medical devices - collection, registration, analysis of information on adverse events;

168) manufacturer of a medical device - an entity in the field of circulation of pharmaceuticals 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 is developed and (or) manufactured by this entity or on its behalf by another entity/individual (entities/individuals), and responsible for its safety, quality and effectiveness;

169) component of a medical device - a part of a medical device that is not an independent medical device, including blocks, parts, elements of a product, materials, spare parts provided by the manufacturer for use in accordance with the functional purpose, performance characteristics, the manufacturer's service manual;

170) safety of a medical device - the absence of an unacceptable risk when using a medical device associated with causing harm to life, human health and the environment;

171) the quality of a medical device - the degree of compliance of the set of properties and characteristics of a medical device with the purposes of its intended use;

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

173) the effectiveness of a medical device - a set of properties and characteristics of a medical device that ensure the achievement of the intended purpose established by the manufacturer of the medical device and confirmed by the practice of its use;

174) medical education - a system of training and advanced training of medical workers, as well as a set of knowledge and skills necessary for a medical worker, obtained during training under training programs for advanced training in medical specialties, confirmed by an official document on the completion of training;

175) assessment of knowledge and skills of students under medical education programs - assessment of the quality of mastering by students of educational programs and the formation of knowledge, skills and abilities in accordance with the stage of training;

176) assessment of the professional qualifications of graduates of medical education programs - a procedure for assessing knowledge and skills, carried out in order to determine whether the qualifications of a graduate of a medical education program meet the requirements of a professional standard in the field of healthcare;

177) strategic partnership in the field of medical education and science is a form of medium-term or long-term cooperation between scientific organizations and educational organizations in the field of healthcare, and foreign organizations of higher and (or) postgraduate education, and medical organizations in the field of medical education and science for implementation and adaptation international standards of education, science and clinical practice on the basis of an agreement;

178) organization of medical education - an organization of education that implements educational programs majoring in "Healthcare";

179) medical care - a complex of healthcare services aimed at maintaining and restoring the health of the population, including drug provision;

180) quality of medical care - the level of compliance of the provided medical care with the standards of medical care;



- 181) healthcare services - actions of healthcare entities with a preventive, diagnostic, therapeutic, rehabilitation and palliative orientation in relation to a specific person;
- 182) independent expertise of the quality of healthcare services (care) - a procedure carried out by independent experts within the framework of internal and external examinations in order to make an opinion on the level of quality of healthcare services (assistance) provided by healthcare entities, using indicators reflecting the indicator of efficiency, completeness and compliance of the provided healthcare services (assistance) with standards;
- 183) medical examination - examination of an individual in order to establish or confirm the fact of the presence or absence of a disease, to determine the state of health;
- 184) medical activity - the professional activity of individuals who have received technical and vocational, post-secondary, higher and (or) postgraduate medical education, as well as legal entities, aimed at protecting the health of the population of the Republic of Kazakhstan;
- 185) a state body in the field of healthcare services (assistance) - a state body that exercises leadership in the provision of healthcare services (assistance), control over the quality of healthcare services (assistance);
- 186) medical devices - materials, products, solutions, reagents, packages, kits used to provide medical care in accordance with the functional purpose and manufacturer's instructions;
- 187) medical rehabilitation - a complex of healthcare services aimed at preserving, partial or complete restoration of the impaired and (or) lost functions of the patient's body;
- 188) medical trains - mobile clinics on railway transport, equipped with the necessary medical equipment, used to ensure the availability and expansion of the list of healthcare services provided to the population living near railway stations (tracks) and in the territories adjacent to them;
- 189) medical equipment - apparatuses, devices, equipment, complexes, systems used separately or in combination with each other to provide medical care in accordance with the functional purpose and operational characteristics established by the manufacturer;
- 190) medical organization - a healthcare organization, the main activity of which is the provision of medical care;
- 191) nursing care – a set of medical services provided by nurses and nurses of extended practice to persons of all ages, groups and communities, sick or healthy, including health promotion, disease prevention and care for the sick, persons with disabilities and dying people;
- 192) preschool and school medicine - the field of medicine, which includes the organization of the provision of medical care to children of preschool and school age, aimed at protecting and promoting health and preventing diseases;

- 193) state pharmaceutical inspector - an official of a state body exercising state control in the field of circulation of pharmaceuticals and medical devices;
- 194) multidisciplinary group - a group of different professionals, formed depending on the nature of the violation of the functions and structures of the patient's body, the severity of his/her clinical condition;
- 195) nicotine - an alkaloid found in tobacco leaves and tobacco smoke;
- 196) advanced therapy pharmaceuticals - pharmaceuticals obtained through biotechnology or bioengineering that offer new opportunities for treatment of diseases and injuries, including means for gene therapy, somatic cell therapy, tissue engineering;
- 197) rehabilitation potential - a clinically justified probability of the prospect of partial or complete restoration of the impaired and (or) lost functions of the patient's body in a certain period of time;
- 198) family therapist - a therapist who has undergone special multidisciplinary training in the provision of primary healthcare to family members and has a certificate of a healthcare professional;
- 199) focal disinfection - disinfection carried out in outbreaks in order to prevent and (or) eliminate infectious and parasitic diseases;
- 200) manufacturer's maximum price – the price for a trade name of a pharmaceutical product provided by the manufacturer, which is the base price for calculating the maximum wholesale and retail prices for a trade name of a medicine, included into the list of medicines that are subject to price regulation, in accordance with the Rules for the regulation of prices for medicines, as well as for medical products within the guaranteed volume free medical care and (or) in the compulsory social health insurance system;
- 201) production site - a territorially separate complex of a manufacturer of pharmaceuticals, medical devices, designed to perform the entire process of manufacturing pharmaceuticals, medical devices or certain stages thereof;
- 202) production control - a set of measures, including laboratory research and testing of products, works and services performed by an individual entrepreneur or legal entity, aimed at ensuring safety and (or) harmlessness to humans and the environment;
- 203) certificate of state registration of products - a document confirming the safety of products (goods), certifying the compliance of products (goods) with technical regulations and (or) unified sanitary and epidemiological and hygienic requirements of the Eurasian Economic Union and issued by a state body in the field of sanitary and epidemiological welfare of the population in a single form;
- 204) product safety monitoring - a system of measures aimed at identifying, preventing and suppressing the import, production, use and sale of products that do not meet the requirements of regulatory legal acts in the field of sanitary and epidemiological well-being of the population;

205) patented pharmaceuticals - pharmaceuticals that have received legal protection in accordance with the legislation of the Republic of Kazakhstan in the field of intellectual property;

206) patient - an individual who is (was) a consumer of healthcare services, regardless of the presence or absence of a disease or condition requiring medical care;

207) prophylaxis - a complex of medical and non-medical measures aimed at preventing the occurrence of diseases, progression in the early stages of diseases and control of already developed complications, damage to organs and tissues;

208) psychoactive substances - substances of synthetic or natural origin (alcohol, narcotic drugs, psychotropic substances, their analogues, other intoxicating substances), which, when taken once, have an effect on mental and physical functions, human behavior, and with prolonged use, cause mental and physical dependence;

209) mental health - a state of well-being, in which each person can fulfill his/her own potential, cope with ordinary life stresses, work productively and fruitfully, and also contribute to the life of their community;

210) medical assistance in the field of mental health - prevention, diagnosis, treatment, medical and social assistance and medical and social rehabilitation of persons with mental, behavioral disorders (diseases);

211) mental, behavioral disorders (diseases) - a group of diseases according to the international classification of diseases characterized by mental impairment;

212) psychological assistance - a set of measures aimed at:

assistance to a person in the prevention, resolution of psychological problems, overcoming difficult life and crisis situations and their consequences, contributing to the maintenance of mental and somatic health, optimization of mental development, adaptation and improving the quality of life, including by activating a person's own capabilities;

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

personal enhancement, self-improvement and self-actualization;

213) psychological problem - a state of mental discomfort of a person caused by dissatisfaction with himself/herself, his/her activities, interpersonal relationships, the situation in the family and (or) other problems of personal life;

214) radiopharmaceutical medicinal product - a medicinal product containing, in a ready-to-use state, one or more radionuclides (radioactive isotopes) as an active substance or as part of an active substance;

215) resident physician - a physician who studies within the educational residency program and works in a medical organization under the supervision of a mentor;

216) residency - the level of postgraduate medical education, the purpose of which is to acquire or change the professional qualifications of a medical specialist in the relevant specialty for admission to independent clinical practice;

217) residency base - a clinic of an educational organization in the field of healthcare, a university hospital, a national center, a scientific center or a research institute, accredited as a medical organization, on the basis of which residency programs are implemented in the manner prescribed by the authorized body;

218) reproductive health - human health, reflecting the ability of an individual to reproduce full-fledged offspring;

219) antiretroviral therapy - a method of treating HIV infection through the use of short and long courses of taking antiretroviral drugs in order to restore the immune system, reduce the risk of developing severe life-threatening diseases, reduce the number of complications and prolong the life of those infected with HIV;

220) reference laboratory - a laboratory of a healthcare organization that carries out organizational and methodological work to implement an external quality assessment system and conduct research in diagnostically complex and expert cases in a certain area of laboratory diagnostics;

221) reference medicinal product - a medicinal product that is used as a comparison drug and is a standard by which the properties of a medicinal product are determined (normalized);

222) recipient - a patient who has undergone a transfusion of donor blood or components and (or) drugs isolated from it, the introduction of male or female donor material (sperm, egg cells, embryos) or organ transplantation (part of an organ) and (or) tissues (part of tissue)) from a donor, as well as artificial organs (parts of organs);

223) health resort treatment - a type of medical rehabilitation carried out in the conditions of temporary stay of persons in a sanatorium organization;

224) health resort organizations - organizations that provide health resort services for the improvement and restoration of human health with the use of medical and other services, natural healing factors, located at resorts or in health-improving areas: a sanatorium (for adults, adults and children, children), student sanatorium-preventorium, children's rehabilitation and health center;

225) sanitary and quarantine control - a type of state control and supervision in the field of sanitary and epidemiological well-being of the population in relation to persons, vehicles and products (goods) controlled by state sanitary and epidemiological control and supervision at checkpoints across the customs border of the Eurasian Economic Union, at interstate transfer railway stations or butt stations in order to prevent the import of products (goods) potentially hazardous to human health, the delivery, emergence and spread of infectious and mass non-infectious diseases (poisoning);

226) sanitary protection zone - a territory separating special-purpose zones, as well as industrial organizations and other production, utilities and storage facilities in a settlement from nearby residential areas, buildings and structures for housing and civil purposes in order to mitigate the impact of adverse factors on them;

227) sanitary and preventive measures - organizational, administrative, engineering and technical, medical and sanitary, preventive and other measures aimed at assessing the risk, harmful effects on humans of environmental factors, eliminating or reducing such risk, preventing the emergence and spread of infectious and mass non-communicable diseases (poisoning) and their elimination;

228) sanitary and epidemiological audit - an alternative form of control of epidemiologically significant facilities subject to state control and supervision in the field of sanitary and epidemiological well-being of the population, in order to identify and assess sanitary and epidemiological risks and develop recommendations for bringing these facilities into compliance with the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of the population;

229) sanitary and epidemiological situation - the state of health of the population and the environment in a certain territory at a certain time;

230) sanitary and epidemiological conclusion - a document certifying compliance with regulatory legal acts in the field of sanitary and epidemiological well-being of the population of facilities of state sanitary and epidemiological control and supervision;

231) sanitary and anti-epidemic measures - measures taken in order to localize and eliminate the emerging foci of infectious, parasitic diseases, poisoning among the population;

232) confidential counseling service- a specially organized service point where preventive services are provided to key populations on a free basis on the basis of anonymity, voluntariness and confidentiality;

233) simulation room (center) - a structural unit of the organization of education in the field of health, on the basis of which the training and delivery of practical skills by students are carried out in the conditions of imitation of clinical practice in a safe learning environment using simulation technologies: mannequins, simulators, computer modeling, virtual reality technologies and specially trained actors trained to portray patients;

234) screening studies - a complex of medical examination of a population that does not have clinical symptoms and complaints, in order to identify and prevent the development of various diseases at an early stage, as well as risk factors for their occurrence;

235) sports medicine - the field of medicine responsible for the biomedical support of the training of athletes and includes medical and functional control in sports, including the admission of athletes to elite sports, functional and medical rehabilitation of athletes, improving sports performance, therapy of somatic diseases of athletes, sports traumatology, emergency medical care in sports and sports hygiene;

236) standard sample - an identified homogeneous substance or mixture of substances intended for use in chemical, physical and biological research, in which its properties are compared with the properties of the investigational medicinal product, and have a purity level sufficient for the respective application;

236-1) strategically important medicines and medical devices – medicines and medical devices intended for medical use in conditions of:

military operations and elimination of their consequences;

occurrence, prevention and elimination of consequences of emergency situations;

threats of emergence, spread of new especially dangerous infectious diseases and elimination of their consequences;

prevention, diagnosis, treatment of diseases and lesions resulting from exposure to adverse chemical, biological, radiation factors, as well as the elimination of their consequences;

absence or threat of absence of medicines or medical products on the markets of the member states of the Eurasian Economic Union in the context of the introduction of restrictive economic measures against at least one of the member states;

237) bone marrow - a tissue that carries out hematopoiesis, located in the inner part of the bones and including hematopoietic stem cells, stroma and other components of the microenvironment;

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

239) internship - a form of non-formal education aimed at the formation and consolidation in practice of professional knowledge, skills and abilities obtained as a result of theoretical training, as well as the study of the specifics of work, advanced experience for further professional activity;

240) mentor - a medical worker with at least five years of experience, appointed by the head of a medical organization or organization of medical education to provide practical assistance in the professional adaptation of students under medical education programs and young specialists, carrying out activities on the basis of the trinity of education, science and practice;

241) risk-oriented approach - a form of quality control of pharmaceuticals and medical devices through annual selection from the market, including in medical organizations;

242) risk assessment - substantiation of the probability 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 potential medico-biological and economic consequences;

243) independent expert - an individual who meets the requirements determined by the authorized body and is included in the register of independent experts;

244) guaranteed volume of free medical care - the volume of medical care provided at the expense of budgetary funds;

245) the maximum price for the trade name of a medicine or medical product within the guaranteed volume of free medical care and (or) in the system of compulsory social health

insurance – the price for the trade name of a medicine or medical product, registered in the Republic of Kazakhstan, above which procurement cannot be made within the guaranteed the volume of free medical care and (or) in the compulsory social health insurance system;

246) the maximum price for the international nonproprietary name of the medicine or the technical characteristics of the medical product within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance – the price of the international nonproprietary name of the medicine or the technical characteristics of the medical product, or the technical characteristics of the medical product above which it cannot to be procured within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

247) tobacco - a plant of genus *Nicotiana* of the family of nightshade of species *Nicotiana Tabacum* and *Nicotiana Rustica*, used for the production of tobacco products;

248) tobacco products - products completely or partially made from tobacco leaf and (or) other parts of a tobacco plant as raw materials prepared in such a way as to be used for smoking, sucking, chewing, sniffing or other methods of consumption, including using systems for heating tobacco or any other device;

249) consumption of tobacco products - the process of consuming a tobacco product, hookah mixture and tobacco for hookah, including the use of a hookah, systems for heating tobacco and any other consumption systems that cause dependence of the human body on nicotine, negatively affecting its health, and on the health of non-tobacco users and polluting the environment;

250) ingredient of a tobacco product - a substance (with the exception of tobacco leaf and other parts of tobacco) used in the manufacture of a tobacco product and present in a finished tobacco product, including in a modified form;

251) packaging of a tobacco product - a unit of group consumer packaging containing a certain number of packs of tobacco products;

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

253) consumer packaging of a tobacco product - packaging intended for sale or primary packaging of tobacco products sold to the end consumer;

254) tobacco sponsorship - any type of contribution to any event, event or individual with the purpose, result or probable result of promoting the sale of a tobacco product or tobacco use, directly or indirectly, with the exception of payments and contributions provided for by the legislation of the Republic of Kazakhstan;

255) system for heating tobacco - a device used to heat tobacco to form an aerosol containing nicotine;

256) tobacco products - a tobacco product packed in consumer packaging;

257) pharmaceutical inspector for good pharmaceutical practices - a person authorized to exercise the functions of conducting pharmaceutical inspection for good pharmaceutical

practices and included in the register of pharmaceutical inspectors of the Republic of Kazakhstan;

258) pharmaceutical inspection for good pharmaceutical practices (hereinafter - pharmaceutical inspection) - an assessment of a facility in the field of drug circulation in order to determine its compliance with the requirements of good pharmaceutical practices of the Republic of Kazakhstan and (or) the Eurasian Economic Union;

259) transplantation - spare-part surgery of organs (part of an organ) and (or) tissues (part of tissue) to another place in the body or into another organism;

260) infectious form of tuberculosis - a form of tuberculosis that poses a danger to others in connection with the release of tuberculosis bacteria into the external environment;

261) electronic consumption systems - electronic systems for the delivery of nicotine and electronic delivery systems for non-nicotine products - devices (including electronic cigarettes) that use electronic technology (battery) to heat liquid (in cartridges, tanks and other containers) from with or without nicotine, other chemicals, fragrances with the formation of an aerosol inhaled by the user;

262) graduate - a person who has mastered the educational program of medical and (or) pharmaceutical education, another educational program in the field of healthcare;

263) tissue - a set of cells and intercellular substance that have the same structure, function and origin;

264) tissue compatibility - the similarity of tissues of a donor and a potential recipient for specific antigens of the HLA system, which determines the compatibility of a donor and a recipient in organ transplantation (part of an organ) and (or) tissues (part of tissue);

265) medical devices for diagnostics outside of a living organism (in vitro) - any instruments, apparatus, devices, equipment, materials, reagents, calibrators, control materials and other products used for medical purposes separately or in combination with each other, as well as together with accessories necessary for the use of these products for their intended purpose, including special software, and intended by the manufacturer of the medical device for use in research outside a living organism (in vitro) of samples of human biological materials to obtain information on the physiological or pathological state, congenital pathology, predisposition to a certain clinical condition or disease, tissue compatibility with a potential recipient, predicting responses to therapeutic interventions, choosing therapeutic agents and/or monitoring treatment;

266) temporary adaptation - the process of removing a person from the state of intoxication and adapting it to the conditions of the environment;

267) a center for temporary adaptation and detoxification - a center designed to provide specialized medical care to persons in a state of alcohol inebriation (intoxication), and which is a structural subdivision of an organization providing medical care in the field of mental health;



268) poisoning - a disease (condition) that occurs during acute (one-time) or chronic (long-term) exposure to a person of chemical, biological and other environmental factors;

269) university hospital - a multidisciplinary medical and preventive structural subdivision of the organization of higher and postgraduate education or a multidisciplinary medical and preventive organization, on the basis of which educational programs of higher, postgraduate and additional medical education are implemented on the basis of modern achievements of science and practice;

270) pharmacovigilance - a type of activity aimed at identifying, analyzing, assessing and preventing unwanted consequences of the use of medicinal products;

271) pharmacovigilance system - a system organized by the holders of registration certificates for medicinal products and the authorized body to perform tasks and responsibilities for pharmacovigilance, designed to monitor the safety of medicinal products, timely identify all changes in the assessment of the “benefit-risk” ratio of medicinal products, develop and implement measures to ensure the use of medicinal products when the benefit exceeds the risk;

272) pharmaceutical workers - individuals with pharmaceutical education carrying out pharmaceutical activities;

273) pharmaceutical education - a system of training and advanced training of pharmaceutical workers, as well as a set of knowledge and skills necessary for a pharmaceutical worker, obtained during training under training and advanced training programs in pharmaceutical specialties, confirmed by an official document on completion of training;

274) pharmaceutical service - the activities of entities in the field of circulation of pharmaceuticals and medical devices related to outpatient drug provision of the population, including the purchase, transportation, storage, accounting and sale of pharmaceuticals and medical devices, within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

275) pharmaceutical activities - activities carried out in the field of public health for the production and (or) manufacture, and (or) wholesale and (or) retail sale of pharmaceuticals and medical devices, related to the purchase (acquisition), storage, import, export, transportation, quality control, design, distribution, use and disposal of pharmaceuticals and medical devices, as well as ensuring their safety, quality and effectiveness;

276) certificate of pharmaceutical product (CPP) - a document issued by an authorized body for the registration of domestic pharmaceuticals abroad and their export;

277) pharmaceutical substance (active pharmaceutical substance) - a medicine intended for the production and manufacture of medicinal products;

278) formulary system - a system of periodic assessment and selection of pharmaceuticals for medicinal formularies, maintaining medicinal formularies and providing information in the form of an appropriate guideline and a list, aimed at the rational use of pharmaceuticals;

279) informed consent - a procedure for a person's written voluntary confirmation of his/her consent to receive medical care and (or) participation in a specific study after receiving information about all aspects of medical care and (or) research that are significant for his/her decision-making. The informed written consent shall be drawn up in the form approved by the authorized body;

280) 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;

281) key population groups - population groups that are at increased risk of contracting HIV infection due to the characteristics of their lifestyle;

282) products that pose a danger to the life and health of the population - the condition of the product, indicating the presence of a risk associated with harmful effects on human health during its use or consumption, recognized as not meeting the safety requirements established by technical regulations, hygiene standards; products that do not have manufacturer's (supplier's) documents confirming their traceability and safety; the marking of which does not meet the requirements of regulatory legal acts; with an unknown or expired shelf life; counterfeit products;

283) sanitary and epidemiological well-being of the population - the state of health of the population, the environment, in which there is no harmful effect on the person of environmental factors and favorable conditions for his/her life are provided;

284) activities in the field of sanitary and epidemiological well-being of the population - the activities of state bodies and organizations in the field of sanitary and epidemiological well-being of the population, aimed at protecting the health of citizens of the Republic of Kazakhstan, including state control and supervision in the field of sanitary and epidemiological well-being of the population, sanitary and epidemiological monitoring, sanitary and epidemiological regulation, state registration of products, sanitary and epidemiological expertise, hygienic training, sanitary and epidemiological audit, disinfection, disinsection and deratization, assessment of the degree of risks in the field of sanitary and epidemiological well-being of the population;

285) state control and supervision in the field of sanitary and epidemiological well-being of the population - the activities of state bodies in the field of sanitary and epidemiological well-being of the population, aimed at preventing, detecting, suppressing and eliminating violations of regulatory legal acts in the field of sanitary and epidemiological well-being of the population, as well as control and supervision of their observance in order to protect health, the environment of the population and the safety of products, processes, services;

286) state body in the field of sanitary and epidemiological welfare of the population - a state body that implements state policy in the field of sanitary and epidemiological welfare of the population, control and supervision over compliance with the requirements established by regulatory legal acts in the field of sanitary and epidemiological welfare of the population and other legislative acts of the Republic of Kazakhstan;

287) surgical sterilization - a method of contraception with the use of medical intervention, as a result of which a woman or a man loses reproductive capacity;

288) live birth and stillbirth of the fetus - the condition of a newborn child (fetus), determined according to the relevant international criteria of the World Health Organization of live birth and stillbirth;

289) smokeless tobacco (nicotine-containing) products - products containing nicotine, completely or partially made from tobacco leaf and (or) other parts of a tobacco plant as raw materials and their synthetic analogs, prepared in such a way as to be used for sucking, chewing, sniffing;

290) restrictive measures, including quarantine, are measures aimed at preventing the spread of infectious and parasitic diseases and providing for a special regime for entrepreneurial and (or) other activities;

291) potentially hazardous chemical and biological substances - substances that, under certain conditions and in certain concentrations, can have a harmful effect on human health or the future generation, the application and use of which is regulated by regulatory legal acts in the field of sanitary and epidemiological welfare of the population;

292) potential recipient - a patient who needs transplantation of tissues (part of tissue) and (or) organs (part of an organ);

293) fundamental biomedical research - biomedical research conducted with the aim of expanding basic knowledge and understanding of the physical, chemical and functional mechanisms of life processes and diseases;

294) euthanasia - the satisfaction of a request to accelerate the death of an incurable patient by any actions or means, including the introduction of drugs or other means, as well as the termination of artificial measures to maintain his/her life in cases of an unfavorable outcome of the disease;

295) epidemic - a massive spread of an infectious disease, significantly exceeding the usually registered morbidity rate;

296) epidemically significant facilities - facilities, manufactured products and (or) activities of which, in violation of the requirements of regulatory legal acts in the field of sanitary and epidemiological well-being of the population, can lead to food poisoning and (or) infectious, parasitic diseases among the population and (or) inflict harm to public health from physical factors, industrial and radioactive contamination;

297) nuclear medicine is a field of medicine in which radioactive elements and ionizing radiation are used for the prevention, diagnosis and treatment of various diseases of human organs and systems, including oncological diseases.

2. The concepts "mental illness", "mental disorder", used in other branches of the legislation of the Republic of Kazakhstan, shall be equivalent to the concept "mental, behavioral disorder (disease)", unless otherwise provided by this Code.

3. The content of other terms shall be determined by separate articles of this Code.

Footnote. Article 1 as amended by the laws of the Republic of Kazakhstan dated 30.12.2021 № 98-VII (shall be enforced upon expiry of sixty calendar days from the date of its first official publication); dated 03.01.2022 № 101-VII (shall be enforced upon expiry of sixty calendar days from the date of its first official publication); dated 27.06.2022 № 129-VII (shall be enforced ten calendar days after the date of its first official publication); dated 04.07.2022 № 134-VII (shall be enforced sixty calendar days after the date of its first official publication); dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication).

## **Article 2. Legislation of the Republic of Kazakhstan in the field of healthcare**

1. The legislation of the Republic of Kazakhstan in the field of public health shall be based on the Constitution of the Republic of Kazakhstan and shall consist 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 other rules than those contained herein, then the rules of the international treaty shall apply.

## **Article 3. Relations regulated by this Code**

1. This Code shall regulate public relations in the field of public health in order to implement the constitutional right of citizens of the Republic of Kazakhstan to health protection.

2. Legal relations regulated by the legislation of the Republic of Kazakhstan in the field of public health shall not be subject to the legislation of the Republic of Kazakhstan on public procurement in terms of procurement:

1) services from healthcare entities for the provision of medical care within the guaranteed volume of free medical care, additional volume of free medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance, except for cases when such procurement is carried out by medical departments of special state bodies;

2) medicines and medical products within the guaranteed volume of free medical care, additional volume of free medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance, except for cases when such procurement is carried out by medical units of special state bodies;

3) services for the storage and transportation of medicines and medical products within the guaranteed volume of free medical care, additional volume of free medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance;

4) goods and services for the examination of state registration, re-registration and amendments to the registration dossier of pharmaceuticals, medical devices and assessment of their safety and quality;

5) pharmaceutical services;

6) services for the registration and sale of pharmaceuticals and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance.

3. Requirements for medical inspection, medical examination in the field of civil aviation for aviation personnel, as well as the categories of persons subject to mandatory medical inspection 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 3 as amended by the law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.07.2022).**

#### **Article 4. Purpose and objective of the legislation of the Republic of Kazakhstan in the field of healthcare**

1. The purpose of the legislation of the Republic of Kazakhstan in the field of public health shall be to ensure the exercise by citizens of the right to health protection, including affordable and high-quality medical care to preserve and strengthen the health of the population of the Republic of Kazakhstan.

2. The objective of the legislation of the Republic of Kazakhstan in the field of public health shall be to create legal conditions aimed at improving the health of citizens of the Republic of Kazakhstan.

#### **Article 5. Principles of the legislation of the Republic of Kazakhstan in the field of healthcare**

Legal regulation of relations in the field of public health shall be based on the principles:

1) ensuring the equality of the rights of citizens of the Republic of Kazakhstan to receive safe, effective and high-quality medical care;

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

3) protection of motherhood and childhood;

4) ensuring the guaranteed volume of free medical care;

5) classifying public health, safety, quality and efficacy of pharmaceuticals as factors of ensuring national security;

6) ensuring the availability of safe, high-quality and effective pharmaceuticals, medical devices and their rational use;

7) social orientation of healthcare, aimed at meeting the needs, demands of the population and improving the quality of life;

- 8) assistance in the formation of a healthy lifestyle and healthy diet;
- 9) priority of preventive activities in the healthcare system;
- 10) availability of medical care;
- 11) continuous improvement of the quality of medical care;
- 12) participation of public associations in ensuring the rights of citizens of the Republic of Kazakhstan to health protection;
- 13) ensuring the sanitary and epidemiological well-being of the population;
- 14) succession of the activities of healthcare entities in the provision of medical care;
- 15) ensuring the continuity and succession of educational activities in the field of public health using modern teaching technologies;
- 16) state support for domestic medical and pharmaceutical science, the introduction of advanced achievements of science and technology in the field of prevention, diagnosis, treatment and medical rehabilitation, innovative development of new pharmaceuticals and technologies, as well as world experience in the field of healthcare;
- 17) encouraging voluntary gratuitous donation;
- 18) state support for domestic developments and the development of a competitive medical and pharmaceutical industry;
- 19) empowering society in matters of health protection;
- 20) coverage of measures to protect and promote health of all categories and groups of the population.

## **Chapter 2. STATE REGULATION AND GOVERNANCE IN THE FIELD OF HEALTHCARE**

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

Government of the Republic of Kazakhstan shall:

- 1) develop the main directions of state policy in the field of healthcare;
- 2) excluded by the Law of the Republic of Kazakhstan dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication);
- 3) excluded by the Law of the Republic of Kazakhstan dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication);
- 4) excluded by the Law of the Republic of Kazakhstan dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication);
- 5) excluded by the Law of the Republic of Kazakhstan dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication);
- 6) excluded by the Law of the Republic of Kazakhstan dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication);
- 7) excluded by the Law of the Republic of Kazakhstan dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication);
- 8) excluded by the Law of the Republic of Kazakhstan dated 19.04.2023 № 223-VII (shall

be enforced ten calendar days after the date of its first official publication);

9) excluded by the Law of the Republic of Kazakhstan dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication).

Footnote. Article 6 as amended by the law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.07.2022); dated 19.04.2023 № 223-VII ( shall be enforced ten calendar days after the date of its first official publication).

#### **Article 7. Competence of an authorized body**

An authorized body shall:

1) implement the state policy in the field of healthcare;

1-1) formulates and implements the state policy in the field of healthcare;

2) organize the formation of a healthy lifestyle and healthy nutrition;

3) excluded by the Law of the Republic of Kazakhstan dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication);

4) introduce new methods of prevention, diagnosis, treatment of diseases and conditions of medical rehabilitation, as well as control over them;

5) carry out monitoring in the field of healthcare;

6) form a list of the guaranteed volume of free medical care;

7) form a list of medical care in the compulsory social health insurance system;

7-1) determines the procedure, types and volume of medical assistance to the population in emergency situations, the introduction of a state of emergency;

8) carry out international cooperation in the field of healthcare, including on educational and scientific activities in the field of healthcare;

9) implement international projects in the field of healthcare;

9-1) defines the national operator in the field of healthcare, its functions and powers;

9-2) defines a single distributor;

10) carry out cross-sectoral coordination of activities for the introduction and implementation of international health regulations;

10-1) develops and approves the list of diseases that are the basis for exemption from fingerprint registration, in coordination with the Ministry of Internal Affairs of the Republic of Kazakhstan;

11) develop and approve the rules for determining cases (events) of a medical incident, recording and analyzing them;

12) recognize the requirements of the world's leading pharmacopoeias as valid in the territory of the Republic of Kazakhstan;

13) carry out state regulation of prices for pharmaceuticals;

14) carry out state regulation of prices for medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

15) determine the list of pharmaceuticals and medical devices purchased from a single distributor;



15-1) determines the procedure for organizing and conducting the purchase of medicines, medical products and specialized medical products within the guaranteed volume of free medical care, additional volume of medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance, pharmaceutical services;

15-2) determines the procedure for the purchase of services for the storage and transportation of medicines and medical products, services for the registration and sale of medicines and medical products by a single distributor within the guaranteed volume of free medical care, additional volume of medical care for persons held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance;

16) determine the priority areas of biomedical research;

17) ensure the development of medical and pharmaceutical science, medical and pharmaceutical education and coordinate scientific and educational activities in the field of healthcare;

18) place a state educational order for training and advanced training of personnel in the field of healthcare;

19) conduct certification for professional competence of the persons specified in paragraph 3 of Article 26 of this Code;

20) participate in the development of a list of professions, works and specialties employed in jobs with harmful working conditions, in favor of which mandatory professional pension contributions are made by agents for the payment of mandatory professional pension contributions at their own expense;

21) form a single long-term plan for the development of healthcare infrastructure;

22) coordinate regional long-term plans for the development of health infrastructure;

23) carry out coordination and methodological guidance of local executive bodies in the field of healthcare;

24) excluded by the Law of the Republic of Kazakhstan dated 30.12.2022 № 177-VII ( shall be enforced ten calendar days after the date of its first official publication);

25) coordinate the activities of healthcare entities;

26) carries out measures to equip state healthcare organizations;

27) coordinate and monitor corporate governance activities in state legal entities in the field of healthcare;

28) determine a unified methodology for organizations entitled to conduct a risk assessment and establish the procedure for conducting a risk assessment;

29) develop and approve a strategy for digitalization of healthcare;

30) create and ensure the functioning of electronic information resources and information systems, information and communication networks in the field of healthcare, organization of



access to them for individuals and legal entities in accordance with the legislation of the Republic of Kazakhstan in the field of informatization;

31) develop and approve, within its competence, regulatory legal acts and forms of accounting and reporting documentation in the field of healthcare;

32) develop and approve standards in the field of healthcare;

33) develop and approve instructions, algorithms and regulations in the field of healthcare ;

34) develop and approve the rules for the use of technical control devices, observation and fixation devices, photo and video equipment used in medical organizations in order to ensure the protection of the rights of patients and medical workers;

35) develop and approve the rules for awarding honorary titles in the field of healthcare;

36) develop and approve the rules of the industry system of incentives;

37) develop and approve a standard system of remuneration for employees of state enterprises on the basis of the right of economic management in the field of healthcare;

38) determine the procedure for attestation of professional competence of health professionals;

39) develop and approve the minimum standards for the provision of regions with medical workers;

40) develop and approve the regulation on the national coordinator for human resources for health;

41) develop and approve the rules for confirming the results of continuous professional development of healthcare workers;

42) develop and approve the nomenclature of specialties and specializations in the field of healthcare, the nomenclature and qualification characteristics of the positions of healthcare workers;

43) develops and approves a list of medicines and medical products purchased by a single distributor under long-term contracts for the supply of medicines and medical products;

44) develop and approve the rules for assessing the quality of pharmaceuticals and medical devices registered in the Republic of Kazakhstan;

45) develop and approve the rules for the formation of the register of healthcare entities engaged in wholesale and retail sales of medical products, in a notification procedure;

46) develop and approve the Kazakhstan National Drug Formulary;

47) develop and approve the rules for the formation of the Kazakhstan National Drug Formulary, the list of pharmaceuticals and medical devices for free and (or) preferential outpatient provision of certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions), as well as the rules for the development of medicinal forms of healthcare organizations;

48) develop and approve the rules for assessing the rational use of pharmaceuticals;

49) develop and approve the Rules for the provision with medicines and medical products within the guaranteed volume of free medical care, additional volume of free medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance;

50) develop and approve the rules for the formation of a list of procurement of pharmaceuticals and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

51) develop and approve the rules for regulating prices for pharmaceuticals, as well as for medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

52) develop and approve the rules for the implementation of service maintenance of medical devices in the Republic of Kazakhstan;

53) develop and approve a methodology for an expert assessment of optimal technical characteristics and clinical and technical justification of medical devices;

54) develop and approve the rules for interaction on contractual fractionation;

55) develop and approve the composition of the first aid kit;

56) develop and approve the rules for the procurement of goods and services for the implementation of expertise during the state registration of pharmaceuticals and medical devices and assessment of their safety and quality;

57) develop and approve a list of pharmaceuticals and medical devices necessary for the provision of emergency and urgent medical care in healthcare organizations;

58) develop and approve regulations on the national coordinator for international health regulations;

59) develop and approve the standard form of the contract for the provision of paid healthcare services (assistance);

59-1) develop and approve the Rules for organizing the provision of medical care to persons with tuberculosis, held in institutions of the penal (penitentiary) system, in agreement with the Ministry of Internal Affairs of the Republic of Kazakhstan;

59-2) develop and approve the Rules for conducting a medical examination of convicts who are presented for release from serving a sentence due to illness, and determines the list of diseases that are the basis for release from serving a sentence, in agreement with the Ministry of Internal Affairs of the Republic of Kazakhstan;

59-3) determine the procedure for procurement and payment for services of healthcare entities on provision of medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budget funds;

59-4) develop and approve model personnel establishment and staff normative standards of medical organizations, providing medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budget funds;

59-5) develop and approve the Rules and methodology for formation of tariffs for medical services, provided within the additional volume of medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budget funds;

59-6) develop and approve minimum standards for equipping with medical equipment and medical devices for medical organizations providing medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budget funds;

60) develop and approve the rules for sending citizens of the Republic of Kazakhstan for treatment abroad and (or) attracting foreign specialists for treatment in domestic medical organizations within the guaranteed volume of free medical care;

60-1) develop and approve the rules for the use of lump-sum pension payments for treatment;

61) develop and approve the methodology for the formation (calculation) of indicators in the field of healthcare;

62) develop and approve the rules for the procurement of services from healthcare entities for the provision of medical care within the guaranteed volume of free medical care and (or) in the compulsory social health insurance system;

63) develop and approve the rules for planning the volume of healthcare services within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

64) develop and approve the rules and methodology for the formation of tariffs for healthcare services provided within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

65) develop and approve tariffs for healthcare services provided within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

66) develop and approve the rules for keeping records of consumers of healthcare services and granting the right to receive medical care in the system of compulsory social health insurance;

67) develop and approve the rules for keeping records of healthcare entities providing medical care within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

68) develop and approve the state standard for the network of healthcare organizations;

69) develop and approve the rules for the formation, coordination and approval of a single long-term plan for the development of health infrastructure;

70) develop and approve the nomenclature of healthcare organizations and regulations on their activities;

71) develop and approve the minimum standards for equipping healthcare organizations with medical devices;

- 72) develops and approves professional standards in the field of healthcare;
- 73) develop and approve the rules for conducting medical examinations of persons applying for the right to drive vehicles;
- 74) develop and approve the rules for conducting a medical examination to establish the fact of the use of a psychoactive substance and the state of intoxication;
- 75) develop and approve the rules for the collection, storage and use of blood and tissues of persons exposed to ionizing radiation;
- 76) develop and approve a list of diseases associated with exposure to ionizing radiation, and the rules for establishing a causal relationship;
- 77) develop and approve a list of medical contraindications for persons with mental, behavioral disorders (diseases) associated with the use of psychoactive substances, for which referral to an organization providing medical care in the field of mental health is not applied;
- 78) develop and approve the rules for the development and revision of clinical protocols;
- 79) develop and approve a methodology for the implementation and assessment of the effectiveness of the implementation of clinical protocols in practical healthcare;
- 80) develop and approve qualification requirements for medical and pharmaceutical activities;
- 81) develop and approve the rules for the provision of medical care by means of mobile medical complexes and medical trains;
- 82) develop and approve the rules for the provision of medical care in accordance with the types established by Article 120 of this Code;
- 83) develop and approve the rules for providing audiological care to the population of the Republic of Kazakhstan;
- 84) develop and approve the nomenclature, rules for the procurement, processing, quality control, storage, sale of blood and its components, as well as the rules for transfusion of blood and its components;
- 85) develop and approve the rules and conditions for the removal, procurement, storage, conservation, transportation, transplantation of organs (part of an organ) and (or) tissues (part of tissue) from a donor to a recipient;
- 86) develop and approve the rules for connecting electronic information resources containing personal medical data to telecommunication networks connecting them with other databases in the field of healthcare, in coordination with the authorized body in the field of information security;
- 87) develop and approve standards, classification systems, reference books and nomenclatures in the field of digital health;
- 88) develop and approve the minimum requirements for medical information systems in the field of healthcare;
- 89) develop and approve the requirements for electronic information resources for remote healthcare services ;

- 90) develop and approve instructions for coding morbidity and mortality, instructions for the use of international classifiers;
- 91) approve the methodology for the formation of the cost of training for education programs in the field of health in agreement with the authorized body in the field of education ;
- 92) determine the procedure and methodology for formation of the demand in medicines and medical products within the guaranteed volume of free medical care, additional volume of free medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance;
- 93) develop and approve the rules for making co-payment;
- 94) develop and approve the rules for the formation of maximum prices and markups for pharmaceuticals and (or) medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;
- 95) form and approve the maximum prices and markups for pharmaceuticals and (or) medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;
- 96) develop and approve the maximum prices for the trade name of the pharmaceutical product for retail and wholesale;
- 97) carries out activities for the formation, monitoring of the process and evaluation of the results of the state social order in the field of public health protection for non-governmental organizations, including for key population groups;
- 98) determine the list of occupational diseases;
- 99) develop and approve the rules for monitoring the fulfillment of the terms of the contract for the purchase of healthcare services from healthcare entities within the guaranteed volume of free medical care and (or) in the compulsory social health insurance system;
- 100) develop and approve the rules for encouraging employees of healthcare entities providing healthcare services within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;
- 101) participate in the formation and implementation of state policy in the field of the medical and pharmaceutical industry;
- 101-1) defines cases of importation into the territory of the Republic of Kazakhstan as humanitarian aid of medicines and medical products that have not passed state registration in the Republic of Kazakhstan;
- 101-2) approves the list of potent substances that have a harmful effect on human life and health;
- 102) develop and approve the rules for organizing the provision of medical care for the period of the imposed state of emergency in accordance with the Law of the Republic of Kazakhstan "On the State of Emergency";

- 103) develop and approve the food standards in healthcare and education organizations;
- 104) develop and approve the rules for conducting a confidential audit in medical organizations;
- 104-1) defines the list of strategically important medicines and medical products;
- 105) perform other functions provided for 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. Article 7 as amended by the Law of the Republic of Kazakhstan dated 02.01.2021 № 399-VI (the procedure for enactment see Art.2); dated 30.12.2021 № 95-VII (shall be enforced from 01.07.2022); dated 27.06.2022 № 129-VII (shall be enforced ten calendar days after the date of its first official publication); dated 04.07.2022 № 134-VII (shall be enforced sixty calendar days after the date of its first official publication); dated 30.12.2022 № 177-VII (shall be enforced ten calendar days after the day of its first official publication); dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication); dated 04.07.2023 № 15-VIII (effective sixty calendar days from the date of its first official publication); dated 23.12.2023 № 50-VIII (effective from 01.01.2024).**

#### **Article 8. Competence of the state body in the field of healthcare services (assistance)**

The state body in the field of healthcare services (assistance) shall:

- 1) implement state policy in the provision of healthcare services (assistance);
- 2) develop and approve, within its competence, legal acts and forms of accounting and reporting documentation in the field of healthcare services (assistance);
- 3) carry out state control in the field of healthcare services (assistance);
- 4) consider cases of administrative offenses in accordance with the Code of the Republic of Kazakhstan on Administrative Offenses;
- 5) carry out licensing of medical activities, with the exception of forensic medical, forensic narcological, forensic psychiatric examinations, in accordance with the Law of the Republic of Kazakhstan "On Permissions and Notifications";
- 6) coordinate the activities of healthcare organizations on control issues in the provision of healthcare services (assistance);
- 7) organize the certification of professional competence of healthcare professionals;
- 8) interact with public associations on issues of state control in the field of healthcare services (assistance);
- 9) develop and approve the rules for accreditation in the field of healthcare;
- 10) develop and approve the rules, timing of post-accreditation monitoring and revocation of the certificate of accreditation in the field of healthcare;
- 11) develop and approve the rules for payment for an independent examination of the quality of healthcare services (assistance), carried out by accredited healthcare entities;

12) carry out the issuance of a license for the import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of organs (parts of an organ) and (or) tissues (parts of tissue) of a person, blood and its components;

13) determine the procedure for issuing conclusions (permits) for the import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of samples of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes for the purpose of unrelated transplantation, germ cells and embryos;

14) carry out the issuance of statements (permits) for the import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and the export from the territory of the Republic of Kazakhstan to these states of organs (parts of an organ) and (or) tissues (parts of tissue) of a person, blood and its components, samples of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes for the purpose of unrelated transplantation, germ cells and embryos;

15) develop and approve the rules for engaging independent experts in the examination of the quality of healthcare services (assistance);

16) develop and approve the requirements for healthcare entities for the provision of services for an independent examination of the quality of healthcare services (assistance);

17) develop and approve the rules for the provision of information (emergency notification) on the cases of death of pregnant women, women in labor, as well as in case of death of women in childbirth within forty-two calendar days after childbirth, sudden death of patients when they are provided with routine medical care (primary healthcare and specialized care, including high-tech healthcare services );

18) develop and approve the rules for maintaining the register of independent experts, as well as the grounds for inclusion in the unified register of independent experts and exclusion from it;

19) forms a state social order, monitors its progress and evaluates the results of citizens' satisfaction with the level and quality of medical care provided in accordance with the legislation of the Republic of Kazakhstan on the state social order, the state order for the implementation of strategic partnership, grants and awards for non-governmental organizations in the Republic of Kazakhstan;

20) monitor the observance by local public health authorities of regions, cities of republican significance and the capital of the state standard of a network of health organizations;

21) carry out state control when health entities appeal the results of monitoring contractual obligations on the quality and volume of healthcare services carried out by the social health insurance fund;

22) develop and approve the rules for organizing the activities of a unified medical information call- center and the regulations for its activities;

23) carry out other functions provided for 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. Article 8 as amended by the Law of the Republic of Kazakhstan dated 04.07.2022 № 134-VII (shall be enforced sixty calendar days after the date of its first official publication).**

## **Article 9. Competence of the state body in the field of sanitary and epidemiological welfare of the population**

The state body in the field of sanitary and epidemiological welfare of the population shall:

1) implement state policy in the field of sanitary and epidemiological welfare of the population;

2) develop and approve, within its competence, legal acts and forms of accounting and reporting documentation in the field of sanitary and epidemiological welfare of the population ;

3) develop and approve the rules for the examination of establishing the connection between occupational disease and the performance of labor (official) duties;

4) carry out sanitary and epidemiological monitoring;

5) exercise state control and supervision in the field of sanitary and epidemiological welfare of the population;

6) coordinate the activities of healthcare organizations operating in the field of sanitary and epidemiological welfare of the population;

7) provide departmental statistical monitoring in the field of sanitary and epidemiological welfare of the population;

8) create and ensure the functioning of electronic information resources and information systems, information and communication networks in the field of sanitary and epidemiological well-being of the population, organizing access to them for individuals and legal entities in accordance with the legislation of the Republic of Kazakhstan on informatization;

**9) excluded by the Law of the Republic of Kazakhstan dated 30.12.2022 № 177-VII (shall be enforced ten calendar days after the date of its first official publication);**

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

11) determine the procedure for maintaining a register of potentially hazardous chemical, biological substances prohibited for use in the Republic of Kazakhstan;

12) determine the hazard class of waste according to the degree of their impact on humans and the environment (according to the degree of toxicity);

13) develop and approve the rules for providing information on medical waste;



14) develop and approve the rules for providing information (emergency notification) about cases of infectious diseases, poisoning to the state body in the field of sanitary and epidemiological welfare of the population;

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

16) organize hygienic education of the population;

17) organize and carry out, within its competence, sanitary-anti-epidemic and sanitary-preventive measures for food poisoning, infectious, parasitic, occupational diseases;

18) issue sanitary and epidemiological conclusions on the compliance of the object of state sanitary and epidemiological control and supervision, draft regulatory documents on maximum permissible emissions and maximum permissible discharges of harmful substances and physical factors into the environment, sanitary protection zones and sanitary protection zones, for new types raw materials and products to regulatory legal acts in the field of sanitary and epidemiological welfare of the population;

19) carry out epidemiological control over infectious and parasitic diseases, over the resistance of pathogens of infectious diseases to antimicrobial drugs, carrying out preventive vaccinations to the population;

20) consider cases of administrative offenses in accordance with the Code of the Republic of Kazakhstan on Administrative Offenses;

21) identify territories (parts of it) free from diseases or with a low level of prevalence of diseases;

22) create sanitary and quarantine points at checkpoints across the State border of the Republic of Kazakhstan, coinciding with the customs border of the Eurasian Economic Union

;

23) develop and approve a list of epidemically significant facilities;

24) monitor compliance with the requirements established by technical regulations;

25) develop and approve the rules of hygienic training for persons of the decreed population group;

26) determine the procedure for assigning registration numbers to food production facilities subject to state control and supervision in the field of sanitary and epidemiological well-being of the population, and maintaining their register;

27) receive notifications of the beginning or termination of activities specified in subparagraphs 1), 2) and 3) of paragraph 1 of Article 24 of this Code, in the manner prescribed by the Law of the Republic of Kazakhstan "On Permissions and Notifications", and also maintain the state electronic register of permits and notifications;

28) determine the procedure for state registration of products, determined by the regulatory legal acts of the Eurasian Economic Union;

29) develop and approve 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 well-being of the population;

30) develop and approve the rules for interaction of state bodies in the conduct of sanitary-anti-epidemic and sanitary-preventive measures;

31) carry out radiation control over compliance with sanitary and epidemiological requirements to ensure the radiation safety of the population;

32) exercise state control and supervision over products subject to state sanitary and epidemiological control and supervision, including food products;

33) develop and approve a list of certain types of food products subject to state control and supervision in the field of sanitary and epidemiological welfare of the population, in the production of which non-iodized salt is used;

34) carry out state regulation in the field of prevention of iodine deficiency diseases;

35) take product samples in accordance with the requirements of regulatory documents;

36) interact with public associations in the field of prevention of non-infectious diseases associated with micronutrient deficiency, including iodine deficiency and iron deficiency diseases;

37) regulate the procedure for the collection, storage, transportation and disposal of medical waste;

38) exercise control over the circulation of medical waste;

39) carry out epidemiological surveillance of non-communicable diseases;

40) develop and approve a list of medical contraindications for concluding an employment contract for heavy work, work with harmful and (or) dangerous working conditions, for underground work, as well as for admission to work of a person belonging to a decreed population group;

40-1) develops and approves qualification requirements for the licensed type of activity for the provision of disinfection, disinsection, deratization services in the field of healthcare;

40-2) issues a license for provision of disinfection, disinsection, deratization services in the field of healthcare in accordance with the Law of the Republic of Kazakhstan "On permits and notifications";

40-3) develops and approves the rules for the formation, record and maintenance of working collections of pathogenic and industrial microorganisms used in the field of sanitary and epidemiological welfare of the population;

40-4) develops and approves the rules for the issuance, renewal, re-issuance, termination of permits for handling of pathogenic biological agents and annexes to them;

40-5) develops and approves qualification requirements for handling pathogenic biological agents;

41) perform other functions provided for 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. Article 9 as amended by the Laws of the Republic of Kazakhstan dated 21.05.2022 № 123-VII (shall be enforced six months after the date of its first official publication); dated 30.12.2022 № 177-VII (shall be enforced ten calendar days after the date of its first official publication).

#### **Article 10. Competence of the state body in the field of circulation of pharmaceuticals and medical devices**

The state body in the field of circulation of pharmaceuticals and medical devices shall:

1) implement the state policy in the field of circulation of pharmaceuticals and medical devices;

2) exercise state control and supervision in the field of circulation of pharmaceuticals, medical devices, as well as over the circulation of narcotic drugs, psychotropic substances and precursors in the field of healthcare;

3) develop and approve, within its competence, legal acts and forms of accounting and reporting documentation in the field of circulation of pharmaceuticals and medical devices;

4) consider cases of administrative offenses in accordance with the Code of the Republic of Kazakhstan on Administrative Offenses;

5) carry out licensing of the types of pharmaceutical activities specified in subparagraphs 1), 2), 3), 4), 5) and 7) of Article 230 of this Code, as well as types of activities related to the circulation of narcotic drugs, psychotropic substances and precursors in the field healthcare;

6) coordinate the activities of healthcare organizations in the field of circulation of pharmaceuticals and medical devices;

7) carry out state registration, re-registration and amendments to the registration dossier, revoke the decision on state registration of pharmaceuticals and medical devices, maintain the State Register of Pharmaceuticals and Medical Devices;

8) coordinate the import (export) of pharmaceuticals and medical devices registered and not registered in the Republic of Kazakhstan;

9) develop and approve the standards of good pharmaceutical practices;

10) receive notifications of the beginning or termination of the activities specified in subparagraphs 4), 5) and 6) of paragraph 1 of Article 24 of this Code, in the manner prescribed by the Law of the Republic of Kazakhstan "On Permissions and Notifications", and also maintain the state electronic register permissions and notifications;

11) issue a certificate for a pharmaceutical product (CPP);

12) issue a permit to conduct an interventional clinical trial of a medicinal product, medical device;

13) make decisions on the suspension of medical use of a pharmaceutical product, medical device by suspending the registration certificate of a pharmaceutical product, medical device, as well as prohibiting medical use and withdrawing from circulation or suspending medical use of a series (batch) of medicinal products and medical devices;

14) conduct accreditation of testing laboratories carrying out monopoly activities for the examination and assessment of the safety and quality of pharmaceuticals and medical devices;

15) develop and approve the rules for the wholesale and retail sale of pharmaceuticals and medical devices;

16) develop and approve checklists, risk assessment criteria and semi-annual schedules for conducting inspections in a regulated area in accordance with the Entrepreneurial Code of the Republic of Kazakhstan;

17) develop and approve the rules for conducting inspections in the field of circulation of pharmaceuticals and medical devices;

18) carry out pharmaceutical inspections;

19) develop and approve the rules for the formation of the pharmaceutical inspectorate, maintaining the register of pharmaceutical inspectors of the Republic of Kazakhstan;

20) develop and approve the rules for selection from the market, including in medical organizations, of pharmaceuticals and medical devices subject to quality control taking into account a risk-based approach;

21) participate in determining the procedure for marking goods and the procedure for exercising control over the circulation of goods subject to marking;

22) perform other functions provided for 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.

#### **Article 11. Competence of central executive bodies and other central state bodies with military medical (medical), forensic medical, forensic narcological, forensic psychiatric subdivisions**

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

1) implement the state policy in the field of healthcare;

2) provide advanced training for employees of military medical (medical) units in accordance with the rules approved by the authorized body;

3) manage the activities of military medical (medical), forensic medical, forensic narcological, forensic psychiatric units;

4) develop and approve the rules of military medical (medical) support;

5) appoint and dismiss the heads of military medical (medical), forensic medical, forensic narcological, forensic psychiatric units;

6) ensure the creation and operation of departmental electronic information resources and information systems, information and communication networks in the field of healthcare;

7) develop and approve the structure of military medical (medical) units, regulations on their activities, unless otherwise provided by the laws of the Republic of Kazakhstan;

8) develop and approve standard staffs and staff standards for military medical (medical), forensic medical, forensic narcological, forensic psychiatric units, unless otherwise provided by the laws of the Republic of Kazakhstan;

9) establish (cancel) restrictive measures, including quarantine, on the territory of troops, units and departmental organizations with simultaneous notification of the state body in the field of sanitary and epidemiological welfare of the population and its territorial subdivision;

10) develop and approve the rules for conducting military medical expertise and regulations on the commissions of military medical expertise in agreement with the authorized body;

11) develop and approve the requirements for the state of health of persons for service in the Armed Forces, other troops and military formations of the Republic of Kazakhstan, state aviation, special state and law enforcement agencies, in agreement with the authorized body;

12) establish the procedure and frequency of medical examinations of the corresponding contingent in military medical (medical) units (organizations);

13) develop and approve forms of departmental military medical (medical) statistical reporting;

14) carry out other functions provided for by the 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 Ministry of Defense of the Republic of Kazakhstan shall develop and approve the requirements for the state of health of persons for service:

1) in the Armed Forces, other troops and military formations of the Republic of Kazakhstan;

2) in the state aviation of the Republic of Kazakhstan.

3. The Ministry of Internal Affairs of the Republic of Kazakhstan shall:

1) develop and approve the rules for conducting military medical expertise in law enforcement agencies and the state courier service of the Republic of Kazakhstan and the regulation on military medical expertise commissions in internal affairs bodies in agreement with the authorized body;

2) develop and approve the requirements for the state of health of persons for service in law enforcement agencies and the state courier service of the Republic of Kazakhstan, in agreement with the law enforcement agencies of the Republic of Kazakhstan.

4. The National Security Committee of the Republic of Kazakhstan shall develop and approve the requirements for the state of health of persons for service in the national security bodies of the Republic of Kazakhstan.

5. The Administrative Department of the President of the Republic of Kazakhstan shall develop and approve:

- 1) the rules for the provision of medical care, including medical rehabilitation, in subordinate organizations;
- 2) the rules for sending medical specialists from subordinate organizations for training, advanced training abroad;
- 3) rules for conducting educational events, attracting foreign consultants;
- 4) other regulatory legal acts in accordance with the legislation of the Republic of Kazakhstan.

**Article 12. Competence of local representative and executive bodies of regions, cities of republican status and the capital**

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

- 1) determine the system of social support measures for medical and pharmaceutical workers sent to work in rural areas and settlements, cities of district and regional significance, as well as the procedure and amount of social support to them at the expense of budgetary funds;
- 2) approve local budgets of healthcare and medical education and reports on their implementation;
- 3) make a decision on the provision of free or reduced fare travel to citizens of the Republic of Kazakhstan outside the settlement of permanent residence to receive high-tech healthcare services within the guaranteed volume of free medical care and (or) medical care in the system of compulsory social health insurance;
- 4) take measures to provide transport in the event of a traveling nature of the provision of medical care to the population within the framework of the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance or reimbursement of transportation costs when leaving for the provision of medical care in rural areas;
- 5) make a decision on the additional provision of a guaranteed volume of free medical care, including pharmaceuticals, specialized medical products, medical devices to certain categories of citizens of the Republic of Kazakhstan with outpatient treatment free of charge and (or) on preferential terms;
- 6) approve measures aimed at the development and operation of healthcare organizations, including organizations, providing medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system;
- 7) determine measures for staffing state healthcare organizations based on the population size in the corresponding administrative-territorial units;
- 8) take a decision on the provision of additional incentives to donors;

9) make a decision on additional staffing and material and technical support of state healthcare organizations in excess of the minimum standard of provision of the region with medical workers approved by the authorized body to provide the population with medical care;

10) carry out planning of the staffing of the region with medical workers and place an order for the training of medical workers in medical education organizations;

11) monitor the provision of social support measures, as well as the training and retention of young professionals who have arrived from medical education organizations;

12) promote the formation of a healthy lifestyle and healthy diet;

13) approve the costs of carrying out measures for the prevention of iodine deficiency diseases as part of local budgets;

14) hear information from the heads of local executive bodies of regions, cities of republican status and the capital, healthcare organizations on the state of work on the prevention of iodine deficiency diseases;

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

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

1) implement the state policy in the field of public health in the territory of the corresponding administrative-territorial unit;

2) ensure the implementation of the rights of individuals to receive a guaranteed volume of free medical care;

3) exercise control over the maintenance of persons in temporary adaptation and detoxification centers;

4) ensure the activities of healthcare organizations that are communal legal entities;

5) organize a set of activities to stimulate a healthy lifestyle;

6) ensure effective planning and use of healthcare resources;

6-1) create medical rehabilitation centers (departments) for children with disabilities in the cities of republican and regional significance, the capital, as well as district centers, including at the facilities of the existing infrastructure of health objects of these settlements, in order to provide rehabilitation services in accordance with the standard of organization of medical rehabilitation, the rules of medical care

7) take measures to improve the quality of healthcare services ;

8) ensure access of the population to information on health issues;

9) ensure the implementation of measures for the development of voluntary gratuitous donation of blood and its components;

10) pay for travel within the country according to the list determined by the local representative bodies of regions, cities of republican status and the capital, to certain

categories of citizens of the Republic of Kazakhstan who travel outside the settlement of permanent residence to receive high-tech healthcare services within the guaranteed volume of free medical care and (or) medical care in the compulsory social health insurance system;

- 11) create local government health authorities;
- 12) appoint and dismiss the heads of local public health administration bodies of regions, cities of republican status and the capital in agreement with the authorized body;
- 13) organize control over staffing of state healthcare organizations;
- 14) take measures for staffing state healthcare organizations, including measures of social support and retention of young professionals;
- 15) take measures for the construction and development of a network of healthcare organizations, their financial and logistical support, including the development of a state network of pharmacies and the creation of pharmacy warehouses;
- 16) coordinate the activities of healthcare entities within the relevant administrative-territorial unit;
- 17) ensure the provision of free medical care with pharmaceuticals and medical devices in emergency situations, the introduction of a state of emergency;
- 18) carry out interregional cooperation in the field of healthcare;
- 19) provide training and advanced training of personnel in the field of healthcare;
- 20) carry out activities necessary for health promotion, prevention of diseases, formation of a healthy lifestyle and healthy nutrition;
- 21) 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;
- 21-1) organize provision of medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system, including preventive measures and treatment of socially significant diseases and diseases that pose a danger to others, including provision with medicines;
- 21-2) organize the provision of medicines and medical products in rural settlements where there are no pharmacies;
- 22) ensure the referral of children with disabilities to psychological, medical and pedagogical consultations with the consent of parents or other legal representatives;
- 23) within the limits of their competence, exercise state control in the field of healthcare;
- 24) excluded by the Law of the Republic of Kazakhstan dated 30.12.2022 № 177-VII ( shall be enforced ten calendar days after the date of its first official publication);
- 25) assist in the execution of the court decision on the direction of citizens of the Republic of Kazakhstan, patients with tuberculosis, for compulsory treatment;
- 26) organize and carry out preventive disinsection and deratization with an assessment of their effectiveness (except for disinsection and deratization on the territory of natural foci of infectious and parasitic diseases, as well as in foci of infectious and parasitic diseases);



27) conduct training of specialists with medical education to sell medicines and medical products in rural settlements through pharmacy points in healthcare organizations providing primary health care, specialized medical care in outpatient settings, and mobile pharmacy points in the absence of a specialist with pharmaceutical education;

28) ensure the implementation of measures for the development of voluntary gratuitous donation of organs (part of an organ) and (or) tissues (part of tissue);

29) develop and approve a regional long-term plan for the development of health infrastructure in agreement with the authorized body;

30) create medical commissions for medical examination of citizens of the Republic of Kazakhstan in the interests of military service and ensure their activities;

31) organize the provision of preschool organizations, educational organizations, healthcare and social protection of the population with iodized food salt and other food products enriched with iodine compounds;

32) carry out activities for the formation, monitoring of the progress and evaluation of the results of the state social order in the field of public health protection for non-governmental organizations, including for key population groups;

33) place a state social order for the provision of palliative care, with the exception of palliative care;

34) assign the nominations "the best professional";

35) ensure the creation of conditions for the placement of interns and resident doctors in healthcare organizations of the corresponding administrative-territorial unit, including the provision of a place of residence and the provision of medical care to interns and resident doctors (if the healthcare organization is located in another settlement with a higher and ( or) postgraduate education);

36) organize the safe disposal of medical waste;

37) carry out the development of a network of healthcare organizations and the implementation of regional long-term plans for the development of healthcare infrastructure;

38) ensure the implementation of state programs for the development of the healthcare system, as well as the implementation of measures in the field of public health and decisions of the National Coordination Council for Health Protection under the Government of the Republic of Kazakhstan;

39) ensure the creation and operation of regional electronic information resources and information systems, information and communication networks in the field of healthcare;

40) exercise, in the interests of local government, other powers assigned to local executive bodies by the legislation of the Republic of Kazakhstan.

**Footnote. Article 12 as amended by the law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.07.2022); dated 03.05.2022 № 118-VII ( shall be enforced ten calendar days after the date of its first official publication); dated 27.06.2022 № 129-VII (shall be enforced ten calendar days after the date of its first official**

publication); dated 04.07.2022 № 134-VII (shall be enforced sixty calendar days after the day of its first official publication); dated 30.12.2022 № 177-VII (shall be enforced ten calendar days after the day of its first official publication).

### **Article 13. Competence of local government health authorities in regions, cities of republican status and the capital**

Local government health authorities of regions, cities of republican status and the capital shall, within their competence:

- 1) implement the state policy in the field of healthcare;
- 2) ensure the implementation of the legislation of the Republic of Kazakhstan in the field of healthcare;
- 3) ensure the implementation of the rights of individuals to receive a guaranteed volume of free medical care;
- 4) organize and carry out monitoring and control over the activities of healthcare entities, with the exception of healthcare organizations operating in the field of sanitary and epidemiological welfare of the population;
- 5) carry out the procurement of pharmaceutical services;
- 6) carry out the purchase and storage of pharmaceuticals, prophylactic (immunobiological , diagnostic, disinfecting) drugs, medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;
- 7) organize the purchase of medical devices, sanitary transport, as well as services for the overhaul of state health organizations;
- 8) organize the provision of the region with personnel in the field of healthcare;
- 9) ensure the maintenance and operation of state medical organizations in accordance with the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of the population;
- 10) provide clinical bases in communal legal entities in the field of public health for educational organizations in the field of healthcare;
- 11) organize the provision of free medical care, the provision of pharmaceuticals and medical devices in emergency situations;
- 12) organize and coordinate activities for training and advanced training of personnel in the field of healthcare;
- 13) organize hygienic training, promotion and formation of a healthy lifestyle and healthy nutrition;
- 14) inform the population about the spread of socially significant diseases and diseases that pose a danger to others;
- 14-1) carry out, together with youth resource centers, information and explanatory, advisory work with young people on issues of reproductive health and family planning, the dangers of gambling addiction (ludomania);

15) interact with international and non-governmental public associations on health protection of citizens of the Republic of Kazakhstan;

16) carry out departmental statistical observations in the field of public health within the relevant administrative-territorial unit in compliance with the requirements of statistical methodology;

17) develop and approve the personal composition of medical commissions created to conduct medical examination of citizens of the Republic of Kazakhstan in the interests of military service, and organize their activities;

18) submit to the authorized body a quarterly report on the implementation of state programs for the development of the healthcare system, as well as on the main quantitative and qualitative indicators of healthcare;

19) make proposals to the authorized body to improve the performance of the healthcare system within the relevant administrative-territorial unit, including on the development of primary healthcare, protection of mothers and children and the implementation of a program for socially significant diseases;

20) organize staffing of the heads of state healthcare organizations in agreement with the authorized body;

21) organize and carry out preventive vaccinations for the population;

21-1) form a special medical commission to conduct a medical examination of convicts on the list of diseases that are the basis for release from serving a sentence;

21-2) provide medical care to persons held in pre-trial detention centers and institutions of the penal (penitentiary) system;

21-3) develop and approve tariffs for medical services provided as part of the additional volume of medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budget funds;

21-4) organizes preventive vaccinations for the population;

21-5) coordinates and monitors activities on corporate governance issues in state legal entities in the field of healthcare in the relevant administrative-territorial units, with the exception of organizations subordinate to the authorized body;

21-6) carries out activities for the formation, monitoring of the implementation and evaluation of the results of the state social order in the field of public health protection for non-governmental organizations, including for key population groups, with the exception of organizations subordinate to the authorized body;

22) exercise, in the interests of local government, other powers assigned to local government health authorities of regions, cities of republican status and the capital by the legislation of the Republic of Kazakhstan.

**Footnote. Article 13 as amended by the law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.07.2022); dated 26.12.2022 № 168-VII ( shall be enforced sixty calendar days after the date of its first official publication); dated**

19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication).

#### **Article 14. Power and authority of the national healthcare operator**

The national healthcare operator shall implement investment projects and public-private partnership projects in the healthcare sector.

#### **Article 15. Joint commission on the quality of healthcare services**

1. The Joint Commission on the Quality of Healthcare services shall be created with the aim of developing recommendations for improving standardization, clinical protocols, standards for quality control and accessibility of healthcare services, as well as accreditation of entities in accordance with Article 25 of this Code.

2. The Joint Commission on the Quality of Healthcare services shall be formed of representatives of state bodies, non-governmental organizations, state and non-state healthcare organizations.

3. The procedure for the formation of a Joint Commission on the Quality of Healthcare services and the regulation on its activities shall be determined by the authorized body.

#### **Article 16. Interdepartmental interaction of state bodies and public associations in the field of healthcare**

1. Interdepartmental interaction of state bodies, public associations and other interested legal entities shall be aimed at reducing risk factors for the occurrence of infectious and non-infectious diseases, and the implementation of measures in emergency situations.

2. An advisory board, the National Coordination Council on Health Protection shall be established to ensure interaction of state bodies, public associations and other interested legal entities under the Government of the Republic of Kazakhstan.

The main task of the National Coordination Council on Health Protection shall be to develop proposals to ensure the implementation of measures provided for by strategic and program documents on health protection of citizens in the Republic of Kazakhstan, to improve state policy, legislation of the Republic of Kazakhstan in the field of healthcare, as well as to determine the main directions in healthcare.

The National Coordination Council on Health Protection shall be created by the Prime Minister of the Republic of Kazakhstan.

3. Local executive bodies shall create regional coordination councils headed by akims of the corresponding administrative-territorial units.

The composition of the regional coordination councils shall be approved by the local representative bodies of the corresponding administrative-territorial unit.

Regional coordination councils on a mandatory and regular basis shall report on their work to the National Coordination Council on Health Protection.

4. The authorized body shall carry out interdepartmental coordination of activities on health protection of citizens of the Republic of Kazakhstan and the maintenance of national records of health personnel resources.

5. State bodies shall interact and implement functions aimed at protecting the health of the population of the Republic of Kazakhstan, within the competence established by the legislation of the Republic of Kazakhstan.

6. Protection of public health shall be carried out with the involvement of local governments, non-governmental organizations and associations through the implementation of social projects and grants at the expense of budget funds, as well as additional sources of funding not prohibited by the legislation of the Republic of Kazakhstan.

7. Public associations for the protection of citizens' rights in the field of health protection shall not be entitled to advertise specific trade names of pharmaceuticals, biologically active food supplements, medical devices, specialized medical food products and breast milk substitutes.

8. Public associations and other non-profit organizations shall deal with the issues of prevention of socially significant diseases, diseases that pose a danger to others, as well as the promotion and formation of a healthy lifestyle.

9. State bodies that have departmental healthcare services shall ensure the submission of departmental reports on the activities of subordinate organizations (subdivisions) of healthcare and the state of health of the assigned contingent to local government bodies of healthcare, with the exception of cases provided for by the laws of the Republic of Kazakhstan.

### **Chapter 3. PERMITS AND NOTIFICATIONS IN THE FIELD OF PUBLIC HEALTH**

#### **Paragraph 1. Licensing in the field of public health**

#### **Article 17. Licensing of activities in the field of public health**

1. The following types of activities shall be licensed in the field of public health:

- 1) medical activities;
- 2) pharmaceutical activities;
- 3) activities related to the circulation of narcotic drugs, psychotropic substances and precursors in the field of healthcare;

4) import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of organs (parts of an organ) and (or) tissues (parts of tissue) of a person, blood and its components;

5) provision of disinfection, disinsection, deratization services in the field of healthcare.

2. The procedure and conditions for issuing and reissuing a license and (or) annex to a license and a duplicate of a license and (or) an annex to a license, exercising permits control, suspension, renewal and termination of a license and (or) annexes to a license to practice medical or pharmaceutical activities shall be established by the laws of the Republic of Kazakhstan "On Permissions and Notifications" and "On Narcotic Drugs, Psychotropic Substances, Their Analogues and Precursors and Counter Measures of Their Illegal Turnover and Their Abuse".

3. The procedure and conditions for the issuance and renewal of a license and a duplicate license, the implementation of permissive control, suspension, renewal and termination of the license for the provision of disinfection, disinsection, deratization services in the field of healthcare are established by the Law of the Republic of Kazakhstan "On permits and notifications".

**Footnote. Article 17 as amended by the Law of the Republic of Kazakhstan dated 21.05.2022 № 123-VII (shall be enforced six months after the date of its first official publication).**

**Article 18. Licensing of the import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of organs (parts of an organ) and (or) tissues (parts of tissue) of a person , blood and its components**

1. Import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of organs (parts of an organ) and (or) tissues (parts of tissue) of a person, blood and its components if they are placed under the customs procedure of export or release for domestic consumption shall be carried out on the basis of a license issued in accordance with the procedure established by the Law of the Republic of Kazakhstan "On Permissions and Notifications".

2. The authorized body, within three working days, shall make a decision on the issue or refusal to issue a license for the import, export of human tissues (parts of tissue), blood and its components, and for the import, export of human organs (parts of an organ) - within one work day.

**Paragraph 2. Permitting procedure and notification procedure in the field of public health**

**Article 19. Permits in the field of public health**

1. Permitting documents in the field of public health shall be:



1) a sanitary and epidemiological conclusion on the compliance of the facility of high epidemic significance with regulatory legal acts in the field of sanitary and epidemiological well-being of the population;

2) permission to handle pathogenic biological agents and its annex;

3) certificate of state registration of products;

4) registration certificate for a pharmaceutical product and medical device;

5) permission to conduct an interventional clinical trial of a pharmaceutical product, medical device;

6) certificate of healthcare specialist .

2. The terms of validity of permits in the field of public health shall be established by the Law of the Republic of Kazakhstan "On Permissions and Notifications".

3. In case of non-fulfillment of the order to eliminate violations of the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare, the officials who issued the permitting document shall suspend its validity on the grounds and in the manner provided for by this Code and the laws of the Republic of Kazakhstan.

4. In case of failure to submit an application for the elimination of violations by the holder of the permit before the expiry of the period for suspension of the permit in the field of public health, the officials who issued the permit shall initiate the revocation of the permit in court within ten working days from the expiration of the specified period.

5. Re-issuance of permits shall be allowed without additional or repeated research (tests), except for subparagraphs 4) and 5) of paragraph 1 of this article, in the following cases:

1) detection of mistakes (misprints) in the document;

2) re-registration of an individual entrepreneur - applicant, change of his/her name or legal address;

3) changes in the name and (or) location of the legal entity - the applicant, manufacturer of products;

4) changing the address of the location of the object without physical displacement.

**Footnote. Article 19 as amended by the Law of the Republic of Kazakhstan dated 21.05.2022 № 123-VII (shall be enforced six months after the date of its first official publication).**

## **Article 20. Issuance of a sanitary and epidemiological conclusion**

A sanitary and epidemiological conclusion shall be issued by a state body in the field of sanitary and epidemiological well-being of the population or a structural subdivision of other state bodies operating in the field of sanitary and epidemiological well-being of the population, based on the results of preventive control and (or) sanitary and epidemiological expertise for:

1) industrial and civil facilities;

2) drafts of regulatory documents on maximum permissible emissions and maximum permissible discharges of harmful substances and physical factors into the environment, zones of sanitary protection;

3) projects for the establishment of calculated (preliminary) and established (final) sanitary protection zones;

4) raw materials and products;

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

#### **Article 21. Issuance of a permit for handling of pathogenic biological agents and its annex**

**Footnote. Title of Article 21 as amended by the Law of the Republic of Kazakhstan dated 21.05.2022 № 123-VII (shall be enforced six months after the date of its first official publication).**

1. A state body in the field of sanitary and epidemiological welfare of the population shall issue a permit for the handling of pathogenic biological agents and an appendix to it to microbiological laboratories, regardless of ownership forms, based on the conclusion of the commission for monitoring compliance with requirements in the field of biological safety (regime commission).

2. The regulations on the commission for monitoring compliance with requirements in the field of biological safety (regime commission) and its composition are approved by the state body in the field of sanitary and epidemiological welfare of the population.

3. For carrying out research, experimental, production, field and diagnostic work with pathogenic biological agents, subject to laboratory containment measures, including engineering, operational and technical requirements (the level of biological safety of the laboratory), a permit is issued for handling pathogenic biological agents and an appendix to it, depending on the risk group used in the work of pathogenic biological agents.

For each facility (stationary or mobile) where activities for handling of pathogenic biological agents will be carried out, a permit for the handling of pathogenic biological agents and an appendix to it, taking into account the pathogenicity group and the degree of danger, indicating the names of pathogenic biological agents, is issued.

4. The basis for issuing a permit for the handling of pathogenic biological agents and its appendices is the compliance of the activities of the entity handling pathogenic biological agents with the qualification requirements for this activity.

5. The grounds for refusal to issue a permit for the handling of pathogenic biological agents and its annexes are:

1) failure to submit or submission of false documents and information necessary to obtain permission to handle pathogenic biological agents and its appendices;

2) the absence of a sanitary and epidemiological conclusion on an object of high epidemic significance;



3) a negative conclusion of the commission for monitoring compliance with requirements in the field of biological safety (regime commission) on the basis of non-compliance with the qualification requirements for handling pathogenic biological agents.

6. The grounds for revoking the permission to handle pathogenic biological agents and its appendices are:

1) failure to eliminate within the prescribed period the violation that was the basis for suspension of the permit for handling of pathogenic biological agents and its annexes;

2) a repeated detection within the last twelve calendar months of a violation that has a dangerous impact on the health of people, animals, plants and the environment, which served as the basis for the suspension of the permit for the handling of pathogenic biological agents and its annexes;

3) other cases provided for by the laws of the Republic of Kazakhstan.

Deprivation or suspension of the permit to handle pathogenic biological agents and its appendices is carried out in accordance with the Code of the Republic of Kazakhstan on administrative offenses.

7. The grounds for termination of the permit for handling of pathogenic biological agents and its annexes are:

1) deprivation of permission to handle pathogenic biological agents and its appendices;

2) cancellation of the permissive order;

3) termination of activity, liquidation of a legal entity;

4) voluntary application of the applicant for termination of the permit for handling pathogenic biological agents and its appendices;

5) other cases provided for by the laws of the Republic of Kazakhstan.

From the moment of termination of the permit for handling of pathogenic biological agents and its annex, it is not allowed to carry out activities for handling of pathogenic biological agents.

**Footnote. Article 21 as amended by the Law of the Republic of Kazakhstan dated 21.05.2022 № 123-VII (shall be enforced six months after the date of its first official publication).**

## **Article 22. Issuance of a certificate of state registration of products**

1. Products determined by the decisions of the Eurasian Economic Union shall be subject to state registration of products in the manner determined by the state body in the field of sanitary and epidemiological welfare of the population.

2. State registration of products shall be carried out on the basis of:

1) expert assessment of the impact on the population and the environment;

2) sanitary and epidemiological expertise for compliance with the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of the population;

3) development of special measures, including the conditions for disposal and destruction of substances and certain types of products, to prevent their harmful effects on the population and the environment.

3. Based on the positive results of the sanitary and epidemiological examination of the submitted documentation and the results of laboratory studies (tests) of products, state registration of products shall be carried out with the issuance of a certificate of state registration of products in terms of their compliance with technical regulations and (or) uniform sanitary and epidemiological and hygienic requirements for goods and technical regulations of the Eurasian Economic Union.

4. The issuance of a certificate of state registration of products shall be denied in the following cases:

1) non-compliance of products with technical regulations and (or) uniform sanitary-epidemiological and hygienic requirements for goods and technical regulations of the Eurasian Economic Union;

2) submission of documents and (or) information containing false information;

3) lack of rights, provided for by the decision of the Eurasian Economic Union or the legislation of the Republic of Kazakhstan, to carry out state registration, as well as the grounds for issuing and issuing a certificate of state registration of products;

4) the impossibility of establishing safety requirements for products and the conditions for their manufacture and circulation, as well as the lack of methods for determining and measuring hazardous factors of such products in products and the environment;

5) the availability of substantiated information obtained within the framework of the accession of a member state to international conventions and treaties on cases of harmful effects of products on human health and the environment during the manufacture, circulation and use (use) of products.

5. The costs associated with the sanitary and epidemiological expertise and scientific substantiation of products subject to state registration shall be borne by the applicants.

6. In addition to the general grounds provided for by the Code of the Republic of Kazakhstan on Administrative Offenses and the Law of the Republic of Kazakhstan "On Permissions and Notifications", the certificate of state registration of products shall be suspended with an indication of the deadline to eliminate the reasons for non-compliance in the following cases:

1) establishment of the fact of non-compliance of products with technical regulations and (or) unified sanitary-epidemiological and hygienic requirements for goods of the Eurasian Economic Union, not related to violations of the conditions of transportation, storage and sale of controlled products;

2) the adoption by the Eurasian Economic Commission of changes in the safety indicators of controlled products, based on the results of the development of the modern level of scientific knowledge;

3) receipt of information from the authorized bodies of the member states of the Eurasian Economic Union, carrying out and (or) coordinating work on technical regulation, sanitary, veterinary and phytosanitary measures, international organizations or states that are not members of the Eurasian Economic Union, on the revealed non-compliance of products with technical regulations and (or) uniform sanitary-epidemiological and hygienic requirements, as well as that the products pose a danger to human life and health.

7. Information on suspension, deprivation (revocation), renewal or termination of the certificate of state registration of products due to its non-compliance with technical regulations and (or) unified sanitary-epidemiological and hygienic requirements for goods of the Eurasian Economic Union shall be immediately sent to the heads (their deputies) authorized bodies of the member states of the Eurasian Economic Union and entered into the Unified Register of Certificates of State Registration of Products.

8. In addition to the general grounds provided for by the Law of the Republic of Kazakhstan "On Permissions and Notifications", the certificate of state registration of products shall be reissued without additional or repeated studies (tests) in the following cases:

- 1) changes in the legal address of the manufacturer of the product or the applicant;
- 2) issuance of a new regulatory legal act of the Eurasian Economic Union, which establishes the requirements for products, the adoption of which does not entail changes in the indicators of hygienic safety, the composition of products.

9. The unified register of certificates of state registration of products shall be subject to placement on the Internet resource of the state body in the field of sanitary and epidemiological welfare of the population.

### **Article 23. Issuance of a registration certificate for a pharmaceutical product or medical device**

1. Pharmaceuticals and medical devices produced in the Republic of Kazakhstan, as well as imported into its territory, shall be subject to state registration, including:

1) pharmaceuticals under trade names indicating the dosage formulation, dosage, packaging from each production site;

2) medical devices under trade names from each production site;

3) consumables for medical devices, except for those specially designed by the manufacturer of the medical device for use with medical devices that can function only with these consumables;

4) medical devices that are part of a specialized vehicle for the provision of medical care;

5) excluded by the Law of the Republic of Kazakhstan dated 04.07.2022 № 134-VII (shall be enforced sixty calendar days after the date of its first official publication);

6) advanced therapy pharmaceuticals manufactured under industrial conditions;

7) medical devices for diagnostics outside of a living organism (in vitro).

1-1. State registration of strategically important medicines and medical devices is carried out in accordance with the procedure determined by the authorized body.

2. The following shall not be subject to state registration:

- 1) pharmaceuticals manufactured in pharmacies;
- 2) pharmaceutical substances (active pharmaceutical ingredients) produced under conditions of good manufacturing practice;
- 3) pharmacopoeial medicinal plant raw materials, including in the composition of fees and consumer packaging;
- 4) medical devices made according to individual orders of patients exclusively for personal use, to which special requirements are imposed in accordance with the appointment issued by a medical professional;
- 5) pharmaceuticals and medical products manufactured in the Republic of Kazakhstan only for export;
- 6) exhibition samples of pharmaceuticals and medical devices for holding exhibitions without the right to their further sale;
- 7) samples of pharmaceuticals and medical devices received for preclinical (nonclinical) and clinical studies and (or) trials;
- 8) laboratory devices not used for the diagnosis of diseases;
- 9) components that are part of medical devices and are not used as an independent product or device;
- 10) radiopharmaceutical medicinal products manufactured directly in healthcare organizations at the place of their use;
- 11) samples of pharmaceuticals and medical devices for examination during state registration;
- 12) pharmaceuticals of advanced therapy manufactured for individual use using autologous biological materials of a patient or his/her donor, selected directly for him/her.
- 13) bulk-products of medicines or medical devices.

3. State registration, re-registration of a pharmaceutical product or medical device, amendments to the registration dossier of a pharmaceutical product or medical device shall be carried out by the state body in the field of circulation of pharmaceuticals and medical devices in the manner determined by the authorized body.

4. A prerequisite for state registration, re-registration and amendments to the registration dossier of a pharmaceutical product or medical device shall be the expertise of the pharmaceutical product or medical device, carried out in the manner determined by the authorized body.

5. A registration dossier shall be submitted to the expert organization containing documents, the list of which is determined by the authorized body, as well as samples of a pharmaceutical product or medical device, standard samples of pharmaceutical substances (active pharmaceutical ingredients) and their impurities in quantities sufficient for threefold analysis, specific reagents and consumables, in exceptional cases and subject to return.

6. The costs associated with the examination of the pharmaceutical product or medical device during their state registration, re-registration and amendments to the registration dossier shall be borne by the applicants.

7. State registration, re-registration, amendments to the registration dossier of a medicinal product or medical device shall be carried out on the basis of an application and a positive opinion of an expert organization on the safety, quality and efficacy of a pharmaceutical product or medical device issued based on the results of the examination.

8. An application for state registration and re-registration, amendments to the registration dossier of a pharmaceutical product or medical device shall be submitted by the developer or manufacturer of the pharmaceutical product or medical device, or their authorized representative.

For state registration, re-registration and issuance of a duplicate of the registration certificate of a pharmaceutical product or medical device, a fee shall be charged in the manner determined by the tax legislation of the Republic of Kazakhstan.

9. Accounting and systematization of documents submitted by the applicant during state registration, re-registration and amendments to the registration dossier of a pharmaceutical product or medical device shall be carried out in the manner determined by the authorized body.

10. By decision of the authorized body, a pharmaceutical product or medical device may be registered under an accelerated expertise procedure.

The order of the accelerated procedure for the examination of a pharmaceutical product or medical device shall be determined by the authorized body.

11. The applicant shall be denied state registration and re-registration and amendments to the registration dossier of a pharmaceutical product or medical device in cases of a negative conclusion based on the results of the expertise of pharmaceuticals and medical devices and failure to submit a full package of documents established in the manner determined by the authorized body.

12. Based on the results of state registration and re-registration of a pharmaceutical product or medical device, a registration certificate shall be issued in the form established by the authorized body.

During the validity period of the registration certificate, the holder of the registration certificate of the pharmaceutical product or the manufacturer of the medical device shall be responsible for the safety, quality and effectiveness of registered pharmaceuticals or medical devices, which must correspond to the registration dossier submitted for the expertise of pharmaceuticals or medical devices for the purposes of state registration, re-registration, introduction of amendments to the registration dossier of a pharmaceutical product or medical device.

13. The decision on state registration of a pharmaceutical product or medical device may be revoked in the manner determined by the authorized body.

14. Pharmaceuticals and medical devices intended for circulation in the customs territory of the Eurasian Economic Union shall be subject to registration according to uniform rules in accordance with the regulatory legal acts of the Eurasian Economic Union.

For registration of domestic pharmaceuticals abroad, the authorized body shall issue a certificate for a pharmaceutical product (CPP) in the manner determined by the authorized body.

15. The state expert organization in the field of circulation of pharmaceuticals and medical devices and the state body in the field of circulation of pharmaceuticals and medical devices shall prohibit, without the consent of the applicant, the disclosure and use for commercial purposes of the confidential information provided for state registration of the pharmaceutical product contained in the application for state registration, materials of the expertise of the pharmaceutical product, as well as the registration dossier of the pharmaceutical product containing new chemical substances, within six years from the date of state registration of the pharmaceutical product.

16. The provisions stipulated in paragraph 15 of this article, which do not allow the disclosure and use of confidential information for commercial purposes, shall not apply to:

- 1) individuals or legal entities who have been issued a compulsory license to use the pharmaceutical product in accordance with the Patent Law of the Republic of Kazakhstan;
- 2) use, production, import, export or distribution of a pharmaceutical product for non-commercial purposes.

17. On the basis of a court decision, the disclosure and use of the information specified in paragraph 15 of this article shall be allowed without the consent of the applicant, in the presence of one of the following cases:

- 1) if the supply of the pharmaceutical product is insufficient to meet the needs of the population within twelve months from the date of registration in the Republic of Kazakhstan;
- 2) revealing of actions that violate the requirements of the legislation of the Republic of Kazakhstan in the field of competition protection.

**Footnote. Article 23 as amended by the Law of the Republic of Kazakhstan dated 04.07.2022 № 134-VII (shall be enforced sixty calendar days after the date of its first official publication).**

#### **Article 24. Notifications in the field of public health**

1. The following activities in the field of public health shall be carried out upon notification:

- 1) hygienic training of decreed population groups;
- 2) activities (operation) of an object of insignificant epidemic significance;
- 3) conducting a sanitary and epidemiological audit;
- 4) wholesale of medical devices;
- 5) retail sale of medical devices;

6) conducting non-interventional clinical trials.

2. Notification on the beginning or termination of the activities specified herein shall be submitted in accordance with the procedure established by the Law of the Republic of Kazakhstan "On Permissions and Notifications".

## **Chapter 4. ACCREDITATION, ASSESSMENT AND CERTIFICATION IN THE FIELD OF PUBLIC HEALTH**

### **Article 25. Accreditation in the field of public health**

1. The following shall be subject to accreditation in the field of public health, carried out by a state body in the provision of healthcare services (assistance):

1) healthcare entities accrediting medical organizations in order to recognize the compliance of the provided healthcare services with the established requirements and standards in the field of public health;

2) organizations that assess the knowledge and skills of students, graduates of professional preparedness and health professionals;

3) healthcare entities, carrying out independent expertise in the field of public health;

4) legal entities that confirm readiness for management activities for certification of health managers;

5) excluded by the Law of the Republic of Kazakhstan dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication);

6) professional medical associations and public associations that carry out activities in the field of public health.

2. Based on an external comprehensive assessment for compliance with accreditation standards, medical organizations shall be subject to accreditation in the field of public health, carried out by healthcare entities accredited by a state body in the field of healthcare services (assistance).

3. Individuals and legal entities for conducting a sanitary and epidemiological audit shall be subject to accreditation in the field of public health, carried out by professional associations in the field of sanitary and epidemiological well-being of the population accredited by the state body in the field of sanitary and epidemiological well-being of the population.

4. Accreditation in the field of public health shall be carried out on a voluntary basis.

5. Accreditation of medical organizations shall be carried out at the expense of a medical organization and shall be an instrument of material and non-material incentives for medical organizations.

Accreditation of medical organizations shall be carried out on the basis of an external comprehensive assessment for compliance with accreditation standards approved by the authorized body, and shall be taken into account when placing the volume of healthcare



services for the provision of a guaranteed volume of free medical care and (or) medical care in the system of compulsory social health insurance, when allocating a state order for training and advanced training of personnel in the field of public health in clinical specialties in higher colleges and organizations of higher and (or) postgraduate medical education.

6. Accreditation of testing laboratories carrying out monopoly activities for the examination and assessment of the safety and quality of pharmaceuticals and medical devices shall be carried out in the manner determined by the authorized body.

7. Individuals specified in paragraphs 1, 2 and 3 of this article, who have passed accreditation in the field of public health, shall be subject to post-accreditation monitoring.

**Footnote. Article 25 as amended by the Law of the Republic of Kazakhstan dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication).**

#### **Article 26. Assessment of professional competence of healthcare specialists**

1. Assessment of professional competence of health specialists shall be a periodically carried out procedure for determining the level of professional competence.

2. Assessment commissions shall be created for the purpose of objective and competent implementation of assessment by the authorized body, local executive bodies, as well as the state body in the field of sanitary and epidemiological welfare of the population.

3. The authorized body shall carry out assessment of the heads of local public health authorities of regions, cities of republican status and the capital and their deputies, heads of organizations subordinate to the authorized body, their deputies.

4. Local government health authorities of regions, cities of republican status and the capital shall carry out assessment of the heads of healthcare organizations subordinate to them

5. The state body in the field of sanitary and epidemiological welfare of the population shall carry out assessment of the heads of health organizations operating in the area of sanitary and epidemiological welfare of the population.

6. Individuals subjected to assessment shall undergo assessment every three years, but not earlier than one year from the date of holding the relevant position.

#### **Article 27. Certification of a healthcare specialist and a manager**

1. Certification of a healthcare specialist shall be carried out by:

1) a state body in the field of providing healthcare services (assistance) in relation to medical workers;

2) a state body in the field of circulation of pharmaceuticals and medical devices in relation to pharmaceutical workers;



3) a state body in the field of sanitary and epidemiological welfare of the population in relation to specialists of the sanitary and epidemiological service.

The list of specialties and specializations of healthcare specialists subject to certification shall be determined by the authorized body.

2. The healthcare specialist certification shall be subject to confirmation every five years.

3. Individuals who have a certificate of a healthcare specialist, with a break of work experience in a specialty for more than three years, shall be allowed to work in a relevant specialty after advanced training, internship and assessment of professional preparedness in an organization accredited by the authorized body.

4. Without an appropriate certificate of a healthcare specialist, the following shall be prohibited:

1) engaging in clinical practice, with the exception of resident doctors, who are admitted to clinical practice (work with patients) under the supervision of a mentor and foreign specialists who have recognized documents on education;

2) engaging in pharmacy practice;

3) implementation of activities in the field of sanitary and epidemiological welfare of the population.

5. Foreign specialists shall be allowed to carry out professional medical activities at Nazarbayev University or its medical organizations, medical organizations of the Department for Presidential Affairs of the Republic of Kazakhstan, as well as for the purpose of training in the organization of higher and (or) postgraduate education, national and scientific centers, scientific -research institutes and higher medical colleges that implement educational curricula of additional education and have passed institutional accreditation by accreditation bodies entered in the register of recognized accreditation bodies on the basis of accredited university hospitals, clinics of educational organizations in the field of public health and the residency base in the manner determined by the authorized body.

6. The rules for certification of a healthcare specialist, confirmation of the validity of a certificate of a healthcare specialist, including foreign specialists, as well as conditions for admission to certification of a healthcare specialist of a person who has received medical education outside the Republic of Kazakhstan shall be developed and approved by the authorized body.

7. Certification of healthcare managers shall be carried out by the state body in the field of healthcare services (assistance) and shall be valid regardless of the implementation of management activities.

8. Certification of a healthcare manager shall be subject to confirmation every five years.

Confirmation of the certificate of a healthcare manager shall be carried out by the state body in the field of healthcare services (assistance).

9. The rules for certification of a healthcare manager, confirmation of the validity of a healthcare manager certificate shall be developed and approved by the authorized body.

10. Suspension or deprivation (revocation) of a certificate of a healthcare specialist shall be carried out in accordance with the laws of the Republic of Kazakhstan.

**Footnote. Article 27 as amended by the Law of the Republic of Kazakhstan dated 08.01.2021 № 410-VI (shall be enforced upon expiration of ten calendar days after the date of its first official publication ).**

## **Chapter 5. STATE CONTROL AND SUPERVISION IN THE FIELD OF PUBLIC HEALTH**

### **Article 28. General provisions on state control and supervision in the field of public health**

1. The implementation of the state policy on state control and supervision in the field of public health shall be recognized as a set of measures aimed at verifying satisfaction and compliance with the requirements of the legislation of the Republic of Kazakhstan, as well as at preventing, detecting, suppressing and eliminating offenses in the field of healthcare.

2. State control and supervision shall be carried out in the areas of:

- 1) the provision of healthcare services (assistance);
- 2) sanitary and epidemiological welfare of the population;
- 3) circulation of pharmaceuticals and medical devices.

3. State supervision in the field of healthcare is carried out in accordance with this Code and the Entrepreneurship Code of the Republic of Kazakhstan.

State control in the field of healthcare is carried out in the form of inspection and preventive control.

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

Preventive control without visiting the entity (object) subject to control shall be carried out in accordance with this Code and the Entrepreneurial Code of the Republic of Kazakhstan

**Footnote. Article 28 as amended by the Law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.01.2023).**

### **Article 29. Procedure for considering a complaint by the appeal commission**

1. Acts on the results of the inspection and an order to eliminate the identified violations issued by officials exercising state control over the provision of healthcare services (assistance), sanitary and epidemiological well-being of the population, circulation of pharmaceuticals and medical devices may be appealed to a higher authority.

2. A complaint against the act on the results of the inspection and the order to eliminate the revealed violations shall be submitted to the name of the head of a higher state body.

3. To consider a complaint on the act following the results of the inspection and the order to eliminate the identified violations, the higher state body shall create an appeal commission, which includes representatives of state bodies in the areas of healthcare services (assistance),

sanitary and epidemiological well-being of the population, circulation of pharmaceuticals and medical products and non-governmental organizations of the Republic of Kazakhstan.

The regulations, provisions and composition of the appeal commissions shall be determined, respectively, by state bodies in the areas of healthcare services (assistance), sanitary and epidemiological welfare of the population, circulation of pharmaceuticals and medical devices.

4. A complaint against the act on the results of the inspection and the order to eliminate the violations revealed by state bodies in the provision of healthcare services (assistance), sanitary and epidemiological well-being of the population, circulation of pharmaceuticals and medical devices shall be considered by the appeal commission within the scope of the contested issues.

5. A complaint against the act on the results of the inspection and the order to eliminate the revealed violations shall be submitted within ten working days after the signing of the act on the results of the inspection.

6. The decision of the appeal commission shall be of a recommendatory nature and shall be submitted to the head of a higher state body. Based on the results of the decision of the appeal commission, the head shall have the right to decide on the recognition of the act on the results of the inspection, the conclusion of preventive control with a visit to the entity (object) subject to control and supervision and the order to eliminate violations of the law as invalid and to annul them in accordance with Article 156 of the Entrepreneurial Code of the Republic of Kazakhstan.

7. The appeal commission shall annually summarize the results of consideration of complaints against acts on the results of the inspection and orders to eliminate violations and develop recommendations for improving the legislation of the Republic of Kazakhstan.

8. In case of dissatisfaction with the superior body of the complaint, the act on the results of the inspection and the order to eliminate violations of the law may be appealed to the court.

9. Information constituting commercial and other secrets protected by law, as well as confidential information shall be provided to members of the appeal commissions when considering a complaint against an act on the results of an inspection and an order to eliminate violations of the law in accordance with the rules developed and approved, respectively, by state bodies in the provision of healthcare services (assistance), sanitary and epidemiological well-being of the population, circulation of pharmaceuticals and medical devices, without obtaining the written permission of the individual who filed the complaint.

#### **Paragraph 1. State control over the provision of healthcare services (assistance)**

#### **Article 30. State control over the provision of healthcare services (assistance)**

1. State control over the provision of healthcare services (assistance) shall be aimed at preventing, detecting, suppressing and eliminating violations of the legislation of the Republic of Kazakhstan in the field of public health by healthcare entities.

2. Entities subject to state control over the provision of healthcare services (assistance) shall be individuals and legal entities that provide healthcare services (assistance).

3. Objects subject to state control over the provision of healthcare services (assistance) shall be divided into two groups:

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

The list of objects of high and low significance subject to state control over the provision of healthcare services (assistance) shall be approved by the state body in the field of healthcare services (assistance) in agreement with the authorized body for entrepreneurship.

4. With regard to objects subject to state control in the field of healthcare services (assistance), control shall be carried out in the form of inspection and preventive control in accordance with the Entrepreneurial Code of the Republic of Kazakhstan.

5. Excluded by the Law of the Republic of Kazakhstan dated 21.05.2022 № 123-VII (shall be enforced from 01.01.2023).

Footnote. Article 30 as amended by the Law of the Republic of Kazakhstan dated 21.05.2022 № 123-VII (shall be enforced from 01.01.2023).

#### **Article 31. Officials exercising state control over the provision of healthcare services (assistance)**

1. Officials exercising state control over the provision of healthcare services (assistance) shall be:

- 1) Chief State Healthcare Inspector of the Republic of Kazakhstan and (or) his/her deputy;
- 2) chief state healthcare inspectors of the relevant administrative-territorial units and their deputies, determined by the head of the state body in the field of healthcare services (assistance);
- 3) specialists of the state body in the field of healthcare services (assistance).

2. Before a decision is made on the application (complaint) of individuals and (or) legal entities against the actions (inaction) of subordinate officials, the superior chief state healthcare inspector in the relevant field shall have the right to suspend the execution, annul or revoke the acts adopted by them.

#### **Article 32. The rights of officials in the exercise of state control over the provision of healthcare services (assistance)**

1. Officials exercising state control in the provision of healthcare services (assistance), in addition to the rights provided for in paragraph 1 of Article 154 of the Entrepreneurial Code of the Republic of Kazakhstan, shall have the right to:

1) involve independent experts in the field of public health in the implementation of state control over the provision of healthcare services (assistance);

2) request and receive from the healthcare entity the necessary information on the provision of healthcare assistance to the population;

3) make copies of the documents necessary for monitoring the provision of healthcare services (assistance), and receive the relevant data (electronic health passports, electronic cards and detailed reports on the changes made to them) from the medical information system of the healthcare entity;

4) initiate the creation of a commission with the involvement of independent experts in the field of public health.

2. Officials exercising state control in the form of preventive control, inspection and investigation are prohibited from making demands and making requests that are not related to the subject of preventive control, inspection or investigation.

3. To make a decision following the results of state control over the provision of healthcare services (assistance), depending on the established violations of the legislation of the Republic of Kazakhstan in the field of public health, officials exercising state control over the provision of healthcare services (assistance) shall issue the following acts:

1) an act on the results of an inspection of a healthcare entity - a document issued by an official exercising state control over the provision of healthcare services (assistance), based on the results of an inspection, preventive control of the entity (object) for its compliance with the requirements of regulatory legal acts in the provision of healthcare services (assistance);

2) an order to eliminate violations of the requirements of regulatory legal acts in the field of healthcare services (assistance);

3) decisions of the chief state healthcare inspectors on:  
suspension of execution or annulment or revocation of acts adopted by lower officials;  
temporary suspension from work of medical workers;  
suspension of activities or certain types of activities of an individual entrepreneur or legal entity in accordance with the laws of the Republic of Kazakhstan.

4. The chief state healthcare inspector of the Republic of Kazakhstan and (or) his/her deputy shall have the right to issue an order to the head of the local government health authority of the region, cities of republican status and the capital, based on the result of the inspection.

**Footnote. Article 32 as amended by the Law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.01.2023).**

**Article 33. Special procedure for conducting inspections in the exercise of state control over the provision of healthcare services (assistance)**

**Footnote. Article 33 is excluded by the Law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.01.2023).**

## **Article 34. Preventive control over the provision of healthcare services (assistance) without visiting the entity (object) subject to control**

1. Preventive control over the provision of healthcare services (assistance) without visiting the entity (object) subject to control shall be carried out in the form of desk audit by analyzing and comparing data from information systems, as well as other information on the activities of the entity (object) subject to control.

2. The objectives of preventive control without visiting the entity (object) subject to control shall be the timely detection, suppression and prevention of violations, granting the healthcare entities (objects) the right to independently eliminate violations revealed by the state body in the provision of healthcare services (assistance) based on the results of preventive control without visiting the entity (object) subject to control, and reducing the administrative burden on them.

3. Preventive control over the provision of healthcare services (assistance) without visiting the entity (object) subject to control shall be carried out no more than once a quarter.

4. If violations are revealed based on the results of preventive control over the provision of healthcare services (assistance) without visiting the entity (object) subject to control, a recommendation shall be made to eliminate the revealed violations. The form of recommendations to eliminate the revealed violations shall be established by the state body in the field of healthcare services (assistance).

5. A recommendation on the elimination of detected violations in the course of preventive control over the provision of healthcare services (assistance) without visiting the entity (object) subject to control shall be sent to the entity (object) subject to control no later than seven working days from the date of detection of violations in one of the following ways:

- 1) by registered mail with notification;
- 2) shall be handed over to the representative and (or) the official of the entity (object) subject to control under signed receipt;
- 3) electronically, to the user's personal account on the web portal of "electronic government".

6. The proper elimination of the identified violations specified in the recommendation on elimination of the identified violations in the course of preventive control over the provision of healthcare services (assistance) without visiting the the entity (object) subject to control shall be deemed the implementation of the recommendation by the entity (object) subject to control, within thirty working days from the day following the day of its delivery (receipt).

7. In case of disagreement with the violations specified in the recommendation, the entity (object) subject to control shall have the right to send an objection to the state body in the field of healthcare services (assistance) within five working days from the day following the day of delivery (receipt) of the recommendation.

8. Failure to comply with the recommendation within the prescribed period on the elimination of the identified violations in the course of preventive control over the provision of healthcare services (assistance) without visiting the entity (object) subject to control shall be the basis for the selection of the entity (object) subject to control for preventive control over the provision of healthcare services (assistance) with a visit to the entity (object) subject to control.

The results of preventive control without visiting the entity (object) subject to control shall be subject to registration by the state body in the field of healthcare services (assistance) and its territorial subdivisions in a special register of preventive control without visiting the entity (object) subject to control, which must be numbered, laced up and sealed by the state a body in the field of healthcare services (assistance) or its territorial subdivision.

### **Article 35. Expertise on the quality of healthcare services (assistance)**

1. Expertise on the quality of healthcare services (assistance) - a set of organizational, analytical and practical measures taken to draw conclusions on the level of quality of healthcare services provided by individuals and legal entities, using indicators reflecting the efficiency, completeness and compliance of healthcare services with standards.

2. Expertise on the quality of healthcare services (assistance) shall be divided into internal and external one.

3. A patient support and internal expertise service shall be created in a medical organization to conduct internal expertise.

The patient support and internal expertise service shall conduct a current analysis of the organization of medical care, the clinical activities of the medical organization, the identification of violations of the procedure for the provision of medical care and standards, a medical incident, as well as consideration within a period not exceeding five calendar days of patient requests.

Based on the results of the expertise, the head of the medical organization shall be made proposals to eliminate the identified causes and conditions for the decline in the quality of healthcare services.

4. An external expertise on the quality of healthcare services (assistance) shall be carried out by:

1) the state body in the field of healthcare services (assistance), including with the involvement of independent experts in the field of public health;

2) the social health insurance fund within the framework of monitoring of the fulfillment of contractual obligations on the quality and volume of healthcare services.

In case of disagreement of the healthcare entity with the results of monitoring of contractual obligations on the quality and volume of healthcare services, the results of monitoring may be appealed to the state body in the field of healthcare services (assistance);

2-1) local government health authorities in relation to medical organizations providing medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system.

In case of disagreement of the healthcare entity with the results of monitoring contractual obligations on the quality and volume of medical services, the results of monitoring can be appealed to the state body in the field of medical services (care);

3) independent experts in the field of public health when they are attracted by individuals or legal entities on a contractual basis;

4) the administration of the Department for the Presidential Affairs of the Republic of Kazakhstan in relation to subordinate organizations.

Based on the results of an external expertise on the quality of healthcare services (assistance) carried out by the state body in the field of healthcare services (assistance) and the social health insurance fund, the state body in the field of healthcare services (assistance) shall conduct an analysis to develop proposals for improving the provision of healthcare services (assistance).

5. The procedure for organizing and conducting internal and external expertise on the quality of healthcare services (assistance) shall be established by the authorized body.

**Footnote. Article 35 as amended by the law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.07.2022).**

## **Paragraph 2. State control and supervision in the field of sanitary and epidemiological welfare of the population**

### **Article 36. State control and supervision in the field of sanitary and epidemiological welfare of the population**

1. State control and supervision in the field of sanitary and epidemiological well-being of the population shall be aimed at preventing, detecting, suppressing and eliminating violations of the legislation of the Republic of Kazakhstan in the field of healthcare, including regulatory legal acts in the field of sanitary and epidemiological well-being of the population, by entities subject to control and supervision.

2. Entities (objects) subject to state control and supervision in the field of sanitary and epidemiological well-being of the population shall be individuals and legal entities, buildings, structures, products subject to state control and supervision in the field of sanitary and epidemiological well-being of the population, equipment, vehicles, soil, water, air and other objects, the activity, use, consumption, application and operation of which may harm the state of human health and the environment.

3. Objects subject to state control and supervision in the field of sanitary and epidemiological welfare of the population (epidemiologically significant objects) shall be divided into two groups:



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

The list of products and epidemiologically significant objects subject to state control and supervision in the field of sanitary and epidemiological well-being of the population shall be approved by the state body in the field of sanitary and epidemiological well-being of the population in agreement with the authorized body for entrepreneurship.

4. In relation to subjects (objects) of state control and supervision in the field of sanitary and epidemiological welfare of the population, control and supervision are carried out in the form of inspection, preventive control, investigation and supervision in accordance with the Entrepreneurial Code of the Republic of Kazakhstan.

4-1. With respect to potentially dangerous biological objects where pathogenic biological agents of I and (or) II pathogenicity groups are handled, with high epidemic significance, control and supervision in the field of sanitary and epidemiological welfare of the population are carried out taking into account the features provided for by the legislation of the Republic of Kazakhstan in the field of biological safety.

5. Excluded by the Law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.01.2023).

Footnote. Article 36 as amended by the Laws of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.01.2023); dated 21.05.2022 № 123-VII ( shall be enforced six months after the date of its first official publication);

### **Article 37. Officials exercising state control and supervision in the field of sanitary and epidemiological welfare of the population**

1. Officials exercising state control and supervision in the field of sanitary and epidemiological welfare of the population shall be:

- 1) Chief State Sanitary Doctor of the Republic of Kazakhstan and (or) his/her deputy;
- 2) chief state sanitary doctors of the corresponding administrative-territorial units (in transport), their deputies, determined by the head of the state body in the field of sanitary and epidemiological welfare of the population;
- 3) specialists of the state body in the field of sanitary and epidemiological welfare of the population;
- 4) chief state sanitary doctors and their deputies, heads and specialists of structural units of the Ministry of Defence of the Republic of Kazakhstan, national security and internal affairs bodies, administrations of the Department for Presidential Affairs of the Republic of Kazakhstan, operating in the field of sanitary and epidemiological welfare of the population.

2. Before a decision is made on the application (complaint) of individuals and (or) legal entities against the actions (inaction) of lower officials, the superior chief state sanitary doctor in the relevant territory shall have the right to suspend the execution, cancel or revoke the acts adopted by them.

## **Article 38. The rights of officials in the exercise of state control and supervision in the field of sanitary and epidemiological welfare of the population**

1. Officials exercising state control and supervision in the field of sanitary and epidemiological welfare of the population, in addition to the rights provided for in paragraph 1 of Article 154 of the Entrepreneurial Code of the Republic of Kazakhstan and other laws of the Republic of Kazakhstan, shall have the right to:

1) prohibit the import, use and sale on the territory of the Republic of Kazakhstan of products intended for use and application by the population, as well as in entrepreneurial and (or) other activities, in case of:

non-compliance with the requirements of technical regulations and (or) the unified sanitary-epidemiological and hygienic requirements of the Eurasian Economic Union;

lack of a certificate of state registration of products;

identification of counterfeit products;

unspecified shelf life and (or) storage, expired shelf life and (or) storage;

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

creating a threat of the emergence and spread of infectious diseases or mass non-infectious diseases and poisoning, including its recognition as dangerous for human health and the environment based on the results of a sanitary and epidemiological examination;

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

inconsistency of objects and production technology with regulatory legal acts in the field of sanitary and epidemiological welfare of the population;

lack of a sanitary and epidemiological conclusion for an object of high epidemic significance;

lack of notification on the activity (operation) of an object of insignificant significance;

lack of production and technological equipment, apparatus, inventory necessary to comply with the technological process of production;

lack of state registration for the first time introduced into production and previously unused substances and materials and preparations made on their basis;

the use of prohibited food additives, ingredients and raw materials;

creating a threat of the emergence and spread of infectious diseases or mass non-infectious diseases and poisoning;

3) make decisions on the temporary suspension from work of persons belonging to the decreed population groups that are a source of infectious and parasitic diseases, as well as those who have not passed mandatory medical examinations in a timely manner, until a laboratory test result and a specialist's conclusion confirming the complete rehabilitation and passing of a mandatory medical examination are received;

- 4) establish restrictive measures, including quarantine, in the relevant administrative-territorial units (at individual facilities);
- 5) send persons who are potential sources of the spread of infectious and parasitic diseases , as well as those who have been in contact with infectious patients, for a medical examination with their suspension from work until the results of a laboratory examination confirming the complete sanitation are received;
- 6) according to indications, send for hospitalization persons who are sources of infectious and parasitic diseases;
- 7) require mandatory vaccination of the population, preventive and focal disinfection, disinsection and deratization in premises and on vehicles, territories, in foci of infectious and parasitic diseases;
- 8) suspend, until the elimination of violations of regulatory legal acts in the field of sanitary and epidemiological well-being of the population, hygienic standards and (or) technical regulations, certain types of work, activities (operation) of facilities subject to state control and supervision in the field of sanitary and epidemiological well-being of the population, in accordance with with the legislation of the Republic of Kazakhstan on administrative offenses;
- 9) prohibit the production, use and sale of new types of raw materials, products, chemicals , technological equipment, mechanisms, processes, tools if they are recognized as dangerous to human life and health;
- 10) conduct a sanitary and epidemiological examination, request the materials necessary to study the assessment of the impact of the examination object on the environment and public health, as well as take samples and select samples of products in quantities sufficient and not exceeding the required volumes for its conduct, without compensation for cost of these products, with the exception of selection made within the framework of product safety monitoring;
- 11) specify requirements for bringing legal acts affecting the issues of sanitary and epidemiological well-being of the population in accordance with regulatory legal acts in the field of sanitary and epidemiological well-being of the population;
- 12) carry out radiation control in the field of sanitary and epidemiological welfare of the population on the territory of the Republic of Kazakhstan;
- 13) establish sanitary protection zones: preliminary (calculated) for operating facilities, established (final) dimensions, and change their dimensions;
- 14) apply to court in case of non-fulfillment or improper fulfillment by individuals or legal entities of acts of officials exercising state control and supervision in the field of sanitary and epidemiological well-being of the population;
- 15) involve specialists from healthcare organizations in the implementation of sanitary and anti-epidemic and sanitary-preventive measures for infectious and parasitic diseases,

poisoning of the population in accordance with the rules for attracting specialists approved by the state body in the field of sanitary and epidemiological welfare of the population.

2. To make decisions on the results of state control and supervision in the field of sanitary and epidemiological well-being of the population, depending on the established violations of regulatory legal acts in the field of sanitary and epidemiological well-being of the population, officials, exercising state control and supervision in the field of sanitary and epidemiological well-being of the population, shall issue the following acts:

1) an act on the results of the inspection - a document issued by an official exercising state control and supervision in the field of sanitary and epidemiological welfare of the population, based on the results of an inspection for compliance with the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of the population;

2) an order to eliminate violations of the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of the population;

3) decisions of the chief state sanitary doctors on:

carrying out sanitary- anti-epidemic and sanitary-preventive measures;

temporary suspension from work of individuals;

prohibiting the import, production, use and sale of products that have a harmful effect on human health, intended for use and application by the population, as well as in business and (or) other activities;

prohibition of the production, use and sale of new types of raw materials, products, chemicals, technological equipment, mechanisms, processes, tools if they are recognized as dangerous to the life and health of people and the environment;

suspension of a permit in the field of public health;

suspension of activities or certain types of activities of an individual entrepreneur or legal entity in accordance with the laws of the Republic of Kazakhstan;

introduction of restrictive measures, including quarantine, in the relevant administrative-territorial units (at individual sites).

### **Article 39. Social protection of officials exercising state control and supervision in the field of sanitary and epidemiological welfare of the population**

Officials of the state body in the field of sanitary and epidemiological well-being of the population, exercising state control and supervision in the field of sanitary and epidemiological well-being of the population, shall have the right to salary uplift in accordance with the unified system of remuneration of workers for all bodies supported by the state budget, approved by the Government of the Republic of Kazakhstan in agreement with the President of the Republic of Kazakhstan.

### **Article 40. Special procedure for conducting inspections in the implementation of state control and supervision in the field of sanitary and epidemiological welfare of the population**

Footnote. Article 40 is excluded by the Law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.01.2023).

**Article 41. State control and supervision in the field of sanitary and epidemiological well-being of the population in the form of an unscheduled inspection**

1. State control and supervision in the field of sanitary and epidemiological welfare of the population in the form of an unscheduled inspection shall be carried out in accordance with the Entrepreneurial Code of the Republic of Kazakhstan.

2. Unscheduled inspections shall be carried out in relation to epidemically significant objects subject to state control and supervision in the field of sanitary and epidemiological welfare of the population.

**Article 42. Preventive control in the field of sanitary and epidemiological welfare of the population with a visit to the subject (object) of control and supervision**

Preventive control in the field of sanitary and epidemiological welfare of the population with a visit to the subject (object) of control and supervision is carried out in accordance with the Entrepreneurial Code of the Republic of Kazakhstan.

Footnote. Article 42 as amended by the Law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.01.2023).

**Article 43. Selection and implementation of sanitary and epidemiological expertise of products**

1. Selection and sanitary and epidemiological expertise of products (goods) shall be carried out to identify, prevent and suppress the 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, without prior notification of the business entity.

The selection of products for sanitary and epidemiological examination shall be carried out by officials of the state body in the field of sanitary and epidemiological well-being of the population and shall be certified by a document confirming the fact of the purchase of products.

Based on the results of sanitary and epidemiological expertise, when revealing products that do not meet the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of the population, the state body in the field of sanitary and epidemiological welfare of the population shall draw up an order to eliminate violations without drawing up a protocol on an administrative offense with a mandatory explanation of the procedure for their elimination, with the exception of cases of detection of products that are dangerous to human life, health and environment, in respect of which an unscheduled inspection of objects shall be carried out in accordance with the Entrepreneurial Code of the Republic of Kazakhstan.

2. Based on the results of the selection and sanitary and epidemiological expertise of products aimed at informing the population on the possible risks associated with the consumption and sale of inappropriate products, the Register of Inappropriate Products shall be posted on the official Internet resource of the state body in the field of sanitary and epidemiological welfare of the population.

**Article 44. Preventive control in the field of sanitary and epidemiological welfare of the population without visiting the subject (object) of control and supervision**

1. Preventive control in the field of sanitary and epidemiological welfare of the population without visiting the subject (object) of control and supervision is carried out by analyzing and comparing data from information systems, as well as other information about the activities of the subject (object) of control and supervision.

2. The objectives of preventive control in the field of sanitary and epidemiological welfare of the population without visiting the subject (object) of control and supervision are:

1) timely detection, suppression and prevention of violations, granting subjects (objects) of control and supervision the right to independently eliminate violations identified by the state body in the field of sanitary and epidemiological welfare of the population based on the results of preventive control without visiting the subject (object) of control and supervision;

2) reducing the administrative burden on them;

3) obtaining reliable information about the impact of the environment on human health in order to make decisions regarding the safety targets of products and services, environmental quality and tools for regulating production processes that potentially have an impact on products, services and the environment;

4) assessment of the effectiveness of measures taken to prevent the occurrence of poisoning and outbreaks of infectious diseases, occupational diseases, the possibility of predicting their occurrence;

5) ensuring compliance with the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of the population;

6) prompt proactive response to emergency situations;

7) formation of a higher level of sanitary and hygienic awareness and responsibility of managers and employees;

8) informing the public about the activities of subjects (objects) for protection of public health and risks to public health.

3. Preventive control in the field of sanitary and epidemiological welfare of the population without visiting the subject (object) of control and supervision is carried out no more than once a quarter.

4. In case of detection of violations based on the results of preventive control in the field of sanitary and epidemiological welfare of the population without visiting the subject (object) of control and supervision, a recommendation is made to eliminate the detected violations, with the exception of desk control. The form of the recommendation on the elimination of

identified violations is established by the state body in the field of sanitary and epidemiological welfare of the population.

5. A recommendation on the elimination of detected violations during preventive control in the field of sanitary and epidemiological welfare of the population without visiting the subject (object) of control and supervision is sent to the subject (object) of control and supervision no later than seven working days from the date of detection of violations in one of the following ways:

- 1) by registered mail with notification;
- 2) is handed over to the representative or official of the subject (object) of control and supervision against receipt;
- 3) electronically to the user's personal account on the e-government web portal.

6. The implementation of the recommendation by the subject (object) of control and supervision is recognized as the proper elimination of identified violations specified in the recommendation on the elimination of identified violations during preventive control in the field of sanitary and epidemiological welfare of the population without visiting the subject (object) of control and supervision, within thirty working days from the day following the day of its delivery (receipt).

7. The subject (object) of control, in case of disagreement with the violations specified in the recommendation on the elimination of the identified violations, has the right to send an objection to the state body in the field of sanitary and epidemiological welfare of the population within five working days from the day following the day of delivery (receipt) of the recommendation on the elimination of the identified violations.

8. Failure to comply within the prescribed period with the recommendation to eliminate the identified violations during preventive control in the field of sanitary and epidemiological welfare of the population without visiting the subject (object) of control and supervision is the basis for selecting the subject (object) of control and supervision for preventive control with a visit to the subject (object) of control and supervision.

9. The results of preventive control without visiting the subject (object) of control and supervision are subject to accounting by the state body in the field of sanitary and epidemiological welfare of the population and its territorial divisions in a special register of preventive control without visiting the subject (object) of control and supervision, which must be numbered, laced and sealed by the state body in the field of sanitary and epidemiological welfare of the population or its territorial subdivision.

**Footnote. Article 44 - as amended by the Law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.01.2023).**

**Article 45. Types of preventive control in the field of sanitary and epidemiological welfare of the population without visiting the subject (object) of control and supervision**

**Footnote. The title of Article 45 as amended by the Law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.01.2023).**

1. Desk audit shall be carried out on the basis of the study and analysis of information on the participants in foreign economic activities, on the applicants who applied for testing, confirmation of product conformity or registration of a declaration of conformity of products, for recognition of the results of confirmation of conformity, on test results, as well as contained in other documents submitted as evidence of the conformity of products submitted to the state body in the field of sanitary and epidemiological welfare of the population by customs authorities, an authorized body in the field of technical regulation.

The objects of the desk audit shall be the participants in foreign economic activities, bodies for confirmation of conformity, testing laboratories (centers), private entrepreneurs, declaring the conformity of products to the requirements of the legislation of the Republic of Kazakhstan.

The list of data required for the implementation of the desk audit, as well as the procedure for their submission by the customs authorities, the authorized body in the field of technical regulation, conformity assessment bodies and testing laboratories (centers) shall be determined by the state body in the field of sanitary and epidemiological welfare of the population.

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

Information on the applicants who have applied for testing, confirmation of product conformity or registration of a declaration of conformity of products, for recognition of the results of confirmation of conformity, on test results, as well as contained in other documents presented as evidence of conformity of products, shall be submitted by the authorized body in the field of technical regulation, bodies for confirmation of conformity and testing laboratories (centers).

Based on the results of the desk audit in case of violation of the requirements of regulatory legal acts in the field of sanitary and epidemiological well-being of the population, hygienic standards and (or) technical regulations, including on the basis of analysis of the comparison of information between imported products and issued, registered, recognized documents on confirmation of conformity for imported products, the state body in the field of sanitary and epidemiological well-being of the population in relation to the entities subject to desk audit shall take the following measures:

1) in relation to the participants in foreign economic activities and private entrepreneurship, declaring the compliance of products with the requirements of the legislation of the Republic of Kazakhstan, engaged in the import and (or) sale of products into the territory of the Republic of Kazakhstan, an order shall be sent to eliminate violations of the requirements of regulatory legal acts in the field of sanitary and epidemiological well-being of the population with mandatory an explanation of the procedure for its elimination;



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

2. Monitoring of the results of the sanitary and epidemiological audit shall be carried out for:

- 1) the information provided on the conducted sanitary and epidemiological audit;
- 2) the presented audit reports on the compliance of the object with regulatory legal acts in the field of sanitary and epidemiological well-being of the population.

As part of the monitoring of the results of the sanitary and epidemiological audit, an analysis shall be carried on the completeness of filling out the audit report on the compliance of the facility with regulatory legal acts in the field of sanitary and epidemiological welfare of the population.

Monitoring of the results of the sanitary and epidemiological audit shall be carried out once every six months.

3. Monitoring of the results of production control is based on transmitted information on the results of production control at epidemiologically significant facilities and on the results of inspections, preventive control with visits.

The entity (object) shall maintain internal records, form and submit periodic reports on the results of production control in accordance with regulatory legal acts in the field of sanitary and epidemiological welfare of the population.

Production control results shall be monitored once every six months.

4. Monitoring of notifications shall be carried out on the basis of the analysis of the received notifications from individuals and legal entities who notified about the beginning and termination of activities in the manner prescribed by the Law of the Republic of Kazakhstan "On Permissions and Notifications", as well as received applications from individuals or legal entities, the results of inspections and preventive control.

Monitoring of notifications shall be carried out at least once every six months.

5. Sanitary and epidemiological monitoring shall be a state system for monitoring the state of health of the population and the environment, their analysis, assessment and forecast, as well as determining the causal relationships between the state of health of the population and the impact of environmental factors.

Analysis, assessment and prognosis - a reasonable assessment of the probability 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 potential biomedical and economic consequences.

Sampling in environmental objects (water, soil, atmospheric air) within the framework of sanitary and epidemiological monitoring shall be carried out at least once a quarter.

Footnote. Article 45 as amended by the Laws of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.01.2023); dated 21.05.2022 № 123-VII ( shall be enforced from 01.01.2023).

#### **Article 46. Sanitary and epidemiological expertise**

1. Sanitary-epidemiological expertise - a complex of organoleptic, sanitary-hygienic, microbiological, virological, parasitological, sanitary-chemical, immunobiological, molecular-genetic, toxicological, radiological, radiometric, dosimetric measurements, measurements of electromagnetic fields and physical factors, other studies and tests as well as examination of projects in order to assess the compliance of projects, products, objects of entrepreneurial and (or) other activities with regulatory legal acts in the field of sanitary and epidemiological well-being of the population.

2. Sanitary and epidemiological examination shall be carried out by state bodies and organizations of the sanitary and epidemiological service within the competence of the decisions or orders of officials of the sanitary and epidemiological service, customs authorities and applications of individuals or legal entities, with the exception of the sanitary and epidemiological examination of projects.

Sanitary and epidemiological examination shall be carried out to determine the possibility of utilization of food products with an expired shelf life stored in the state material reserve.

Sanitary and epidemiological examination of projects - part of the examination of projects , carried out as part of a comprehensive non-departmental examination of projects (feasibility studies and design estimates) intended for the construction of new or reconstruction ( expansion, technical re-equipment, modernization) and overhaul of existing facilities, complex urban planning expertise of urban planning projects.

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

Sanitary and epidemiological expertise in terms of sanitary and epidemiological laboratory research shall be carried out by state organizations in the field of sanitary and epidemiological welfare of the population.

3. Sanitary and epidemiological expertise of construction projects shall be carried out on:

1) projects (feasibility studies and design estimates with the establishment of the size of the estimated (preliminary) sanitary protection zone) intended for the construction of epidemically significant objects, by state or accredited expert organizations as part of a comprehensive non-departmental examination;

2) urban planning projects subject to approval by the Government of the Republic of Kazakhstan or local representative bodies of regions, cities of republican status and the capital

4. Sanitary and epidemiological expertise for projects not provided for in paragraph 3 of this article shall be carried out by state bodies in the field of sanitary and epidemiological well-being of the population, structural divisions of other state bodies carrying out activities in the field of sanitary and epidemiological well-being of the population, for:

1) industrial and civil facilities;

2) drafts of regulatory documents on maximum permissible emissions and maximum permissible discharges of harmful substances and physical factors into the environment, sanitary protection zones and health protection areas, for raw materials and products;

3) products subject to state control and supervision in the field of sanitary and epidemiological welfare of the population, including the coordination of shelf life and storage conditions for food products;

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

#### **Article 47. Procedure for conducting sanitary and epidemiological laboratory tests**

1. Sanitary and epidemiological laboratory studies shall be the part of the sanitary and epidemiological expertise associated with organoleptic, sanitary and hygienic, microbiological, virological, parasitological, sanitary and chemical, immunobiological, molecular genetic, toxicological, radiological, radiometric, dosimetric measurements, measurements of electromagnetic fields and physical factors, other research and testing.

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

2. Sanitary and epidemiological laboratory tests of food products subject to state control and supervision in the field of sanitary and epidemiological well-being of the population shall not be carried out if:

1) expired shelf life;

2) obvious signs of poor quality (spoilage, decomposition, pollution).

3. Chemical and biological substances recognized as hazardous to human health or future generations based on the results of sanitary and epidemiological expertise and scientific expertise shall be prohibited for use in the Republic of Kazakhstan.

The register of hazardous chemical, biological substances prohibited for use in the Republic of Kazakhstan shall be subject to publication on the official Internet resource of the state body in the field of sanitary and epidemiological welfare of the population.

4. Upon the request of individuals or legal entities to carry out sanitary and epidemiological expertise, they shall provide funding and the necessary documentation.

#### **Article 48. Sanitary and epidemiological audit**

1. Sanitary and epidemiological audit shall be carried out by an auditor included in the state electronic register of permits and notifications.

2. A sanitary and epidemiological audit shall be carried out upon the request of the owners of facilities subject to state control and supervision in the field of sanitary and epidemiological well-being of the population, on the basis of an agreement for a sanitary and epidemiological audit concluded between the applicant and the auditor in accordance with the Civil Code of the Republic of Kazakhstan.

3. Annually, by January 10 after the reporting year, auditors shall be obliged to provide the state body in the field of sanitary and epidemiological welfare of the population with information on the audit conducted in the form approved by the state body in the field of sanitary and epidemiological welfare of the population.

4. The results of the sanitary and epidemiological audit shall be reflected in the auditor's report with conclusions on the conformity or non-conformity of the facility.

5. An auditor's report with conclusions on the compliance of the facility with the requirements of regulatory legal acts in the field of sanitary and epidemiological well-being of the population shall be submitted by the auditor to the territorial subdivision of the state body in the field of sanitary and epidemiological well-being of the population no later than five working days from the date of completion of the audit.

6. The results of the sanitary and epidemiological audit cannot be the basis for the exemption of objects of high epidemiological significance from inspections.

#### **Article 49. Requirements to auditors carrying out activities for conducting sanitary and epidemiological audit**

1. To conduct a sanitary and epidemiological audit, individuals and legal entities must meet the following qualification requirements:

1) for individuals:

higher medical education of a sanitary and epidemiological specificity;

work experience in the relevant specialty for at least ten years;

accreditation to carry out activities related to sanitary and epidemiological audit;

2) for legal entities - availability of qualified personnel in the staff that meets the requirements established by subparagraph 1) of this paragraph.

2. Before and after the termination of the sanitary and epidemiological audit, individuals and legal entities must notify about it the state body in the field of sanitary and epidemiological welfare of the population in accordance with the procedure established by the Law of the Republic of Kazakhstan "On Permissions and Notifications."

3. Auditors carrying out activities for the conduct of a sanitary and epidemiological audit shall be obliged to:

1) ensure a comprehensive, objective, high-quality audit;

2) comply with the requirements of regulatory legal acts in the field of sanitary and epidemiological well-being of the population, other regulatory legal acts;

3) conduct an audit in the field of sanitary and epidemiological welfare of the population on the basis of documents of state regulation.

4. It shall be prohibited to conduct a sanitary and epidemiological audit by the auditor, the executors of which:

1) are in labor relations or are close relatives or in-laws of officials of the audited entity, as well as a shareholder (participant) owning ten or more percent of shares (stakes in the authorized capital) of the audited entity;

2) are associated with personal property interests with the audited entity;

3) dismissed from state bodies and organizations of sanitary and epidemiological supervision for committing corruption offenses.

5. In accordance with the laws of the Republic of Kazakhstan, auditors shall be liable for poor-quality and improper performance of their duties and the audit report issued by them on the compliance of the facility with regulatory legal acts in the field of sanitary and epidemiological welfare of the population.

#### **Article 50. Sanitary-epidemiological auditing procedure**

1. The sanitary-epidemiological auditing procedure includes:

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

2) preliminary analysis of documents submitted by an applicant;

3) the conclusion of an agreement on the sanitary-epidemiological audit;

4) the setting of goals of the sanitary-epidemiological audit;

5) the development of a plan for conducting the sanitary-epidemiological audit;

6) the sanitary-epidemiological audit (inspection of a facility, analytical treatment of materials, comparative analysis and assessment of the level of danger to public health of a planned or ongoing activity, the sufficiency and reliability of rationales for the facility's sale);

7) preparation of an auditor's report and its submission to the applicant.

2. To have a sanitary-epidemiological audit conducted, an applicant shall provide funding for it and submit such documents as:

1) an application for a sanitary-epidemiological audit;

2) materials related to the facility, which is subject to the sanitary-epidemiological audit:

certificates of inspections conducted by state bodies for the sanitary-epidemiological welfare of the population for a previous year (if such certificates aren't available - for previous years);

a sanitary-epidemiological opinion on the facility's compliance with the requirements of regulatory legal acts in the field of the sanitary-epidemiological welfare of the population or a notice of commencement of business;

3) previous opinions of the sanitary-epidemiological audit, if any, and documentation on the management system of the economic entity;

4) other materials required for the facility's appraisal

3. Based on the results of the sanitary-epidemiological audit carried out in accordance with the plan, an auditor's report is drawn up on the facility's compliance with sanitary rules in the form established by the sanitary-epidemiological auditing procedure.

4. The sanitary-epidemiological auditing procedure is determined by the state body for the sanitary-epidemiological welfare of the population.

5. The results of the sanitary-epidemiological audit are invalidated if the preparation of the auditor's report was associated with:

1) the violation of the sanitary-epidemiological auditing procedure;

2) a failure to comply with the requirements of regulatory legal acts in the field of the sanitary-epidemiological welfare of the population.

#### **Article 51. Production control**

1. Individual entrepreneurs and legal entities operating at facilities, which are subject to control and supervision in the field of the sanitary-epidemiological welfare of the population, shall develop, document, introduce an effective production control system and keep it in good working order.

2. It is the responsibility of an individual entrepreneur or the head of a legal entity to ensure production control.

3. An individual entrepreneur or a legal entity appoints persons responsible for ensuring the timeliness, completeness and reliability of production control.

4. The purpose of production control is to ensure the safety and (or) harmlessness of products, works and services for a person by organizing and conducting self-control, at the facility, over compliance with the requirements of regulatory legal acts in the field of the sanitary-epidemiological welfare of the population.

5. Production control includes:

1) the development of a production control program;

2) the implementation (organization) of laboratory research and measurements in accordance with the requirements of regulatory legal acts in the field of the sanitary-epidemiological welfare of the population;

3) control over the timeliness and completeness of medical examinations;

4) control over the availability of documents confirming products' safety and conformity;

5) the assessment of risk factors, analysis of identified hazards, safety criteria and (or) harmlessness of industrial and environmental factors, and determination of methods for controlling the safety of processes;

6) keeping records and reporting of documentation related to the implementation of production control;

7) the development of a scheme for informing the population, local executive bodies, the state body for the sanitary-epidemiological welfare of the population on emergency situations, suspension of production, breakdowns in technological processes, mass (three or more cases) infectious and parasitic, occupational diseases related to the facility's operation and poisoning that pose a threat to the sanitary-epidemiological welfare of the population;

8) control over the implementation of measures specified in the production control program.

6. The production control program is developed by an individual entrepreneur, a legal entity independently or with the involvement of persons carrying out a sanitary-epidemiological audit.

7. The production control program is subject to revision when introducing a new technology, changing the technological process, formula of a food product, and in case of other changes affecting the stability of the sanitary-epidemiological situation and (or) posing a threat to the sanitary-epidemiological welfare of the population.

8. Requirements for the implementation of production control are established in the sanitary rules approved by the state body for the sanitary-epidemiological welfare of the population.

### **Clause 3. State control in the field of distribution of medicines and medical products**

#### **Article 52. State control in the field of distribution of medicines and medical products**

1. State control in the field of distribution of medicines and medical products is aimed at preventing, identifying, suppressing and eliminating violations of the legislation of the Republic of Kazakhstan in the field of healthcare and regulatory legal acts in the field of distribution of medicines and medical products by the subjects of control.

2. Healthcare entities selling medicines and medical products, carrying out pharmaceutical activities, as well as legal entities exercising control over the quality of raw materials, medicines and medical products, the state expert organization in the field of distribution of medicines and medical products are subject to state control.

3. State control in the field of distribution of medicines and medical products is carried out in the form of:

1) conducting inspections in accordance with the Entrepreneurial Code of the Republic of Kazakhstan;

2) preventive control with a visit to the subject of control in accordance with the Entrepreneurial Code of the Republic of Kazakhstan;

3) preventive control without visiting the subject (object) in accordance with this Code.

4) inspections carried out for compliance with qualification or licensing requirements for issued permits, requirements for sent notifications in accordance with the Law of the Republic of Kazakhstan "On permits and notifications";

5) investigations.

**Footnote. Article 52 as amended by the Law of the Republic of Kazakhstan dated 21.05.2022 № 123-VII (shall be enforced from 01.01.2023).**

**Article 53. Officials exercising state control in the field of distribution of medicines and medical products**

1. Officials exercising state control in the field of distribution of medicines and medical products are:

1) the Chief State Pharmaceutical Inspector of the Republic of Kazakhstan and (or) his/her deputy;

2) state pharmaceutical inspectors of structural units of the state body for the distribution of medicines and medical products;

3) chief state pharmaceutical inspectors in respective territories, who are appointed by the head of the state body for the distribution of medicines and medical products;

4) state pharmaceutical inspectors of territorial units of the state body for the distribution of medicines and medical products.

2. Given of an application (complaint) for (against) actions (inaction) of lower officials from individuals and (or) legal entities, a higher-ranking chief state pharmaceutical inspector in a relevant field has the right to suspend, cancel or revoke acts issued by lower officials until a decision on such an application (complaint) is made.

**Article 54. Rights of officials exercising state control in the field of distribution of medicines and medical products**

1. In addition to the rights specified in paragraph 1 of Article 154 of the Entrepreneurial Code of the Republic of Kazakhstan, officials exercising state control in the field of distribution of medicines and medical products are entitled to:

1) select samples of medicines and medical products for examination;

2) withdraw medicines and medical products from distribution in accordance with the legislation of the Republic of Kazakhstan;

3) prohibit and (or) suspend the import, production, manufacture, storage, use and sale in the Republic of Kazakhstan of medicines and medical products that have become unusable, with an expired shelf life, falsified, counterfeit medicines and medical products and those failing to meet the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare;

4) visit facilities operating in the field of distribution of medicines and medical products to check their compliance with the requirements of the legislation of the Republic of Kazakhstan;



5) receive information, departmental statements on the distribution of medicines and medical products from entities in the field of distribution of medicines and medical products.

2. To make a decision on the results of state control in the field of distribution of medicines and medical products depending on identified violations of regulatory legal acts in the field of distribution of medicines and medical product, officials exercising state control in the field of distribution of medicines and medical products issue such acts as:

1) an audit findings report - a document issued by an official exercising state control in the field of distribution of medicines and medical products pursuant to the results of inspection, preventive control of the subject (object) for its compliance with the requirements of regulatory legal acts in the field of distribution of medicines and medical products;

2) an order to eliminate violations of the requirements of regulatory legal acts in the field of distribution of medicines and medical products;

3) decisions of chief state pharmaceutical inspectors on:  
prohibiting the import, production, use and sale of medicines and medical products failing to meet the requirements of regulatory legal acts in the field of distribution of medicines and (or) the requirements of the Eurasian Economic Union, posing a threat to human life and (or) health;

suspending a license and (or) annex to a license for pharmaceutical activity and (or) another permit in the field of healthcare in accordance with the laws of the Republic of Kazakhstan;

suspending or canceling or withdrawing acts adopted by lower officials.

3. Officials exercising state control in the form of preventive control, inspection and investigation are prohibited from making demands and making requests that are not related to the subject of preventive control, inspection or investigation.

**Footnote. Article 54 as amended by the Law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.01.2023).**

### **Article 55. Preventive control in the field of distribution of medicines and medical products without visiting the subject (object) of control**

1. Preventive control in the field of distribution of medicines and medical products without visiting the subject (object) of control is carried out by way of analyzing and comparing data from information systems, as well as other information on the activity of the subject (object) of control.

2. The objectives of preventive control without visiting the subject (object) of control are timely identification, suppression and prevention of violations, enabling the subjects (objects) of control to independently eliminate violations identified by the state body for the distribution of medicines and medical products based on the results of preventive control without visiting the subject (object) control, and reducing the administrative burden on them.

3. Preventive control in the field of distribution of medicines and medical products without visiting the subject (object) of control is carried out no more than once a quarter.

4. If violations are identified pursuant to the results of preventive control in the field of distribution of medicines and medical products without visiting the subject (object) of control, it is necessary to issue a recommendation to eliminate the identified violations. The form of the recommendation to eliminate the identified violations is established by the state body for the distribution of medicines and medical products.

5. A recommendation on the elimination of violations identified in the course of preventive control in the field of distribution of medicines and medical products without visiting the subject (object) of control is sent to the subject (object) of control within seven working days of violations' identification in one of the following ways:

- 1) by registered mail with return receipt;
- 2) it is handed over against receipt to his/her/its representative and (or) an official of the subject (object) of control;
- 3) electronically to the user's personal account on the "e-government" web portal.

6. The recommendation shall be deemed as complied with by the subject (object) of control if identified violations, specified in the recommendation on elimination of the violations identified in the course of preventive control in the field of distribution of medicines and medical products without visiting the subject (object) of control, are eliminated within thirty working days of a day following the day of its delivery (receipt).

7. In case of disagreement with the violations specified in the recommendation, the subject (object) of control has the right to send an objection to the state body for the distribution of medicines and medical products within five working days of a day following the day of the recommendation's delivery (receipt).

8. A failure to comply with a recommendation on the elimination of violations identified in the course of preventive control in the field of distribution of medicines and medical products without visiting the subject (object) of control within the prescribed period is a ground for selecting the subject (object) of control for preventive control in the field of distribution of medicines and medical products with a visit to the subject (object) of control.

9. The results of preventive control without visiting the subject (object) of control are subject to registration by the state body for the distribution of medicines and medical products and its territorial units in a special register of preventive control without visiting the subject (object) of control, which shall be numbered, bound and bear the seal of the state body for the distribution of medicines and medical products or its territorial unit.

10. Preventive control in the field of distribution of medicines and medical products without visiting the subject (object) of control is carried out in relation to:

- 1) medicines and medical products within the guaranteed volume of free medical care and (or) compulsory social health insurance, as well as medicines subject to co-payment;
- 2) all medicines.

## **Chapter 6. HEALTHCARE ADVERTISING**

### **Article 56. Healthcare advertising**

1. Medicines and medical products are advertised in the manner prescribed by the state body for the distribution of medicines and medical products.

Biologically active additives are advertised in the manner prescribed by the state body for the sanitary-epidemiological welfare of the population.

Medical services (assistance) are (is) advertised in the manner prescribed by the state body for medical services (assistance).

2. The advertising of medical services, methods and means of prevention, diagnosis, treatment and medical rehabilitation (for the purposes of this article, hereinafter referred to as services), medicines and medical products, biologically active additives shall be reliable, recognizable without special knowledge or the use of special means, exclude comparisons with other services, medicines and medical products, biologically active additives, not mislead consumers by abuse of their trust, also in relation to characteristics, composition, consumer properties, cost (price), intended results of use, research and test results.

3. It is prohibited to:

1) advertise medicines and medical products, biologically active additives, means of prevention that are not registered in the Republic of Kazakhstan;

2) advertise prescription medicines in the media;

3) distribute, for advertising purposes, samples of medicinal products dispensed with medical prescription;

4) use children, their images and voices in advertising medicines and medical products, except for medicines and medical products for children;

5) distribute and place advertisements of medicines and medical products, biologically active additives in public transport vehicles, organizations that are not related to their prescription, use and dispensing, except for advertisements of medicines at medical, pharmaceutical conferences, congresses, symposia and others scientific meetings;

6) place advertising information on industrial products, prescription forms;

7) place outdoor (visual) advertising of medicines and medical products;

8) use healthcare professionals authorized to prescribe medicines and medical products as advertisers, except for the cases of providing reliable information on medicines and medical products for scientific or educational purposes, and also for informing patients;

9) advertise services in the absence of a license for the relevant type of activity;

10) advertise services provided by persons without a certificate of a healthcare specialist, including foreign specialists;

11) indicate, in public advertising, methods of treatment of such diseases as sexually transmitted diseases, oncological, mental, behavioral disorders (diseases), dangerous infectious diseases, HIV infection, TB disease, diabetes mellitus;

12) refer, in advertising, to the recommendations of scientists, healthcare specialists, as well as officials of state bodies, who may encourage the use and (or) prescription of medicines and medical products;

13) present services, medicines and medical products, biologically active additives in advertising as unique, safest and most effective;

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

15) cause assumptions that the effectiveness of the service provided, of treatment with an advertised medicinal product, biologically active additive is guaranteed, that the use of the product does not develop side effects;

16) provide information in advertising that is not directly related to the advertised service, medicine and medical product;

17) advertise proposals for entering into transactions on human organs (parts of an organ) and (or) tissues (parts of tissue).

4. It is allowed to distribute and place advertisements of services, medicines and medical products in the media, electronic information resources in healthcare organizations.

5. Advertising of medicines shall contain complete (including appropriate restrictions on the use of the medicine) and reliable information, the exclusion of which may entail inappropriate use of medicines or unjustified risk for the consumer.

6. Control over the production, distribution and placement of advertising is carried out by state bodies within their competence.

## **Chapter 7. DIGITAL HEALTH**

### **Article 57. Fundamental principles of digital health**

The principles of digital health are as follows:

1) implementation of healthcare principles through digitalization of data and processes in the industry;

2) the primacy of standards, which are a tool for the implementation of policy and strategy, the basis of the methodology determined by the authorized body;

3) ensuring the protection of the objects of informatization of healthcare, containing personal health data of individuals, the safety and confidentiality of personal health data of individuals, as well as the patient's access to his/her personal data;

5) support to improve the efficiency of the healthcare system;

6) support to improve the quality of medical services.

Footnote. Article 57 as amended by the Law of the Republic of Kazakhstan dated 02.01.2021 № 399-VI (shall be enforced upon expiration of ten calendar days after the date of its first official publication ).

#### **Article 58. Basic terms used in this chapter**

The following basic terms are used in this chapter:

1) digitization of healthcare - the use of digital technologies to transform medical and administrative-managerial processes in healthcare, aimed at increasing the accessibility, efficiency, quality and safety of medical assistance;

2) personal health data - personal data containing information on the health of an individual and medical services provided to him/her, which are recorded on electronic, paper or other physical media;

3) personal health data aggregator - an operator of personal data that collects, processes, stores, protects and provides personal medical data in accordance with the rules approved by the authorized body;

4) the owner of personal health data – the subject of personal medical data (individual) in respect of whom these data are generated;

5) the national telemedicine network of the Republic of Kazakhstan - a network of stationary and mobile telemedicine centers of healthcare organizations under the jurisdiction of the authorized body, which are united by secure telecommunications infrastructure and equipped with hardware and software complexes;

6) telemedicine services - the provision of medical services for the purpose of diagnosis, treatment, medical rehabilitation and prevention of diseases and injuries, conducting research and assessments using digital technologies, providing remote interaction of healthcare professionals with one another, with individuals and (or) their legal representatives, identification of these persons, as well as documenting their actions;

7) medical information system - an information system for electronic maintenance of processes of public health entities;

8) mobile healthcare - the use of mobile devices, including mobile phones, pocket personal computers, medical and other devices for healthcare purposes;

9) wearable medical devices - mobile (wearable) devices designed to collect and transmit indicators of the health status of an individual;

10) telehealth - telemedicine services, including clinical diagnosis and monitoring of an individual's condition at a distance, as well as other non-clinical functions such as disease prevention, health promotion, public health support, health education and scientific medical research;

11) telemedicine network - a network of stationary and mobile telemedicine centers having medical equipment and united by information and communication technologies into a

single information space for the provision of telemedicine services, training and exchange of medical information in electronic format;

12) National electronic health passport - an electronic information resource of the authorized body containing electronic health passports, which is available to both an individual and healthcare workers in accordance with the rules approved by the authorized body;

13) digital health facility - electronic information resources, software, mobile healthcare technologies, healthcare information and communication infrastructure;

14) the owner of a digital health facility- a digital health entity entitled to own and use objects of informatization;

15) digital health entity - individuals and legal entities, state bodies that carry out activities or enter into public relations in the field of digital health;

16) electronic health passport - a set of structured personal health data on the state of health of an individual and medical assistance provided to him/her, which are generated by digital health entities from electronic sources throughout his/her life and available to both an individual and healthcare workers in accordance with the rules approved by the authorized body;

17) electronic medical record - a set of structured personal health data related to a specific case of medical assistance.

**Footnote. Article 58 as amended by the Law of the Republic of Kazakhstan dated 02.01.2021 № 399-VI (shall be enforced upon expiration of ten calendar days after the date of its first official publication ).**

## **Article 59. Activities in the field of digital health**

1. Activities in the field of digital health include:

1) legal regulation, development and approval of digital health standards;

2) development of information and communication infrastructure of the healthcare industry;

3) provision of individuals and legal entities with data and information in the field of healthcare;

4) collection, processing, storage, protection of personal health data;

5) provision of information and communication services for the collection, processing, storage, protection and provision of personal health data;

6) transition to paperless medicine.

2. Electronic information resources, through which telemedicine services are provided, shall comply with the requirements of the authorized body.

3. The authorized body processes, stores and protects personal health data to be stored at the national level.

4. An individual has the right to delegate the storage and processing, protection of his/her personal health data to digital health entities in accordance with the rules approved by the authorized body.

#### **Article 60. Interaction of digital health facilities and entities**

1. Collection, processing and storage of personal health data for the formation of electronic medical records containing personal health data are carried out as part of medical assistance, taking into account the patient's informed consent to receive medical assistance.

1-1. It is prohibited to collect or process copies of identity documents, with the exception of identity documents of immigrants.

2. Public health entities are obliged to ensure the transfer of data to the National electronic health passport and electronic information resources of the authorized body to the extent and in the frequency determined by the authorized body, except for the cases provided for by the Law of the Republic of Kazakhstan "On State Secrets".

3. Personal health data are transferred to third parties with the consent of an individual, except for the cases specified in paragraph 4 of this article.

4. Personal health data are transferred to the National electronic health passport and electronic information resources of the authorized body without the consent of an individual, as well as to public health entities, only for the purpose of providing medical assistance and in the cases specified in:

1) paragraph 1 of Article 137 of this Code;

2) the Law of the Republic of Kazakhstan "On Personal Data and Their Protection".

5. Personal health data aggregators provide information and communication services for the collection, processing, storage, protection of personal health data by public health entities.

6. Digital health entities generate, store, protect electronic medical records in accordance with the rules approved by the authorized body.

7. Wearable medical devices are subject to certification in accordance with the legislation of the Republic of Kazakhstan.

**Footnote. Article 60 as amended by the Law of the Republic of Kazakhstan dated 11.12.2023 № 44-VIII (shall be enforced upon expiration of sixty calendar days after the day of its first official publication).**

#### **Article 61. Responsibility of digital health entities**

1. The right to access the personal health data of an individual with his/her consent is granted to:

1) providers of medical and pharmaceutical services;

2) an organization responsible for reimbursing expenses related to health services delivery in order to reimburse expenses related to health services delivery;

3) the authorized body, local public health authorities of regions, cities of republican significance and the capital, territorial units of the authorized body for social protection of the population, state bodies exercising state control in the field of medical services (assistance), sanitary-epidemiological welfare of the population, distribution of medicines and medical products;

4) military-medical (medical) units of central executive bodies and other central state bodies in relation to the served contingent;

5) legal entities that collect, process, store, protect and provide personal health data in accordance with the legislation of the Republic of Kazakhstan.

These organizations can access personal health data only to the extent required to provide relevant services.

2. In cases of emergency and urgent medical services, it is implied that public health entities providing such forms of medical services are given access to personal health data of an individual.

3. The transfer of personal health data of an individual is prohibited, except for the cases provided for by this Code and the laws of the Republic of Kazakhstan.

4. The persons specified in paragraph 1 of this Article, shall be granted the right to access personal health data of an individual in accordance with the procedure, determined by the rules for delimiting access rights of digital healthcare subjects, approved by the authorized body, in agreement with the authorized body in the field of personal data protection.

5. An individual has the right to access information on his/her health and medical services provided to him/her, which is contained in the National electronic health passport, electronic health passport, and also to track the data access log.

6. The relationship of the health data aggregator with public health entities is regulated by the civil legislation of the Republic of Kazakhstan.

7. Healthcare professionals and workers of public health entities are liable under the laws of the Republic of Kazakhstan for the quality, timeliness, reliability and confidentiality of electronic data entered into the electronic information resources of the authorized body.

8. The persons are liable under the laws of the Republic of Kazakhstan for a failure to comply with measures to protect personal health data, which results in the loss, illegal collection and processing of personal health data relating to the private life of individuals, including those falling under medical confidentiality.

9. For carrying out analytical, statistical activities, scientific and other research, personal health data shall be used in anonymized form.

**Footnote. Article 61 as amended by the Law of the Republic of Kazakhstan dated 02.01.2021 № 399-VI (shall be enforced upon expiration of ten calendar days after the date of its first official publication ).**

## **Article 62. Security of personal health data of individuals**



1. Security features of electronic information resources containing personal health data shall be established in accordance with the legislation of the Republic of Kazakhstan on informatization and on personal data and its protection.

2. It is not allowed to use electronic information resources containing personal health data for causing pecuniary and (or) non-pecuniary damage, restricting the exercise of rights and freedoms guaranteed by the laws of the Republic of Kazakhstan.

3. Information obtained from electronic information resources containing personal health data of individuals is used solely for performing official duties.

**Footnote. Article 62 as amended by the Law of the Republic of Kazakhstan dated 02.01.2021 № 399-VI (shall be enforced upon expiration of ten calendar days after the date of its first official publication ).**

## **Chapter 8. STRUCTURE OF THE HEALTHCARE SYSTEM**

### **Article 63. Public health entities**

1. The healthcare system consists of the public and private health sectors.

2. The public health entities are healthcare organizations, as well as individuals engaged in private medical practice and pharmaceutical activities.

3. The public health sector consists of state bodies for healthcare, healthcare organizations set up on the basis of the state property right, as well as military-medical (medical) units and organizations that carry out expertise in the field of forensic (forensic-medical, forensic-narcological, forensic-psychiatric) medicine.

4. The private health sector consists of healthcare organizations set up on the basis of the private property right, as well as individuals engaged in private medical practice and pharmaceutical activities.

5. Individuals have the right to engage in private medical practice if they have a certificate of a healthcare specialist, at least five years of work experience in a relevant specialty and a medical license.

### **Article 64. Types of medical activities**

Medical activities have such types as:

- 1) medical assistance;
- 2) laboratory diagnostics;
- 3) postmortem diagnostics;
- 4) activities in the field of procurement of blood and its components;
- 5) activities in the field of sanitary-epidemiological welfare of the population;
- 6) activities in the field of public health protection;
- 7) educational and scientific activities in the field of healthcare;
- 8) expertise in the field of healthcare;

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

## **Article 65. Development of the healthcare infrastructure**

1. Facilities of healthcare infrastructure are buildings and structures, property complexes used in the implementation of medical, pharmaceutical and educational activities in the field of healthcare.

2. The healthcare infrastructure is developed on the principles of:

1) improving the quality and accessibility of medical care for all groups of the population, including the adaptation of medical facilities for persons with disabilities and other groups of the population with disabilities;

2) using advanced international experience in the design and construction of multidisciplinary stationary complexes;

3) ensuring equal opportunities for public and private investments and increasing the investment attractiveness of the health sector for domestic and foreign investors;

4) strategic planning of the development of the healthcare infrastructure.

3. A single long-term plan for the development of infrastructure is a republican plan, which is developed on the basis of regional long-term plans for the development of healthcare infrastructure and approved by the authorized body. The requirements established as part of the development of regional long-term plans for the development of healthcare infrastructure are:

1) bringing the network of healthcare organizations in line with the state standard for the network of healthcare organizations;

2) bringing public health facilities into compliance with the requirements of regulatory legal acts on the sanitary-epidemiological welfare of the population, architectural, urban planning and construction activities, and equipment standards;

3) bringing the bed capacity of hospitals and the production capacity of organizations providing primary care services and (or) consultative-diagnostic assistance in line with the needs of the population;

4) the opening of healthcare infrastructure facilities based on the needs of the population, ensuring access to medical services.

4. Central state bodies, local executive bodies and the autonomous educational organization take measures to maintain and operate medical facilities under their jurisdiction in accordance with the requirements of regulatory legal acts on the sanitary-epidemiological welfare of the population, architectural, urban planning and construction activities, and equipment standards.

5. Investment planning and development of the network of healthcare organizations are carried out in accordance with regional long-term plans for the development of healthcare infrastructure.

6. Long-term plans for the development of healthcare infrastructure are developed for a ten-year period.

**Footnote. Article 65 as amended by the Law of the Republic of Kazakhstan dated 27.06.2022 № 129-VII (shall be enforced ten calendar days after the date of its first official publication).**

#### **Article 66. Public-private partnership in the field of healthcare**

1. The operation of a public health facility created (reconstructed) as a result of implementation of a concession project in the field of healthcare (hereinafter referred to as a concession object) is the use of a concession object, which may provide for technical and functional maintenance, in the manner and on the conditions determined by a concession agreement in the health sector (hereinafter referred to as a concession agreement).

2. The maintenance of a concession object is its use, including the implementation of a complex of technological and organizational measures aimed at keeping the concession object in a good, safe condition suitable for its functional maintenance, as well as its current and (or) major repairs, management, implementation of service and (or) auxiliary activities in the manner and on the conditions determined by a concession agreement.

3. Functional maintenance of a concession object is its use as intended, and also for the production of goods and (or) the performance of works, and (or) the provision of services in the manner and on the conditions determined by a concession agreement.

4. A functional operator in the field of healthcare - a state-owned legal entity or a legal entity with one hundred percent participation of the state or its subsidiary, more than fifty percent of the voting shares (participation shares) of which belongs to it on the basis of the right of ownership, whose statutory activity is the provision of medical care, which are not a party to the concession agreement, intended for the implementation of activities related to functional maintenance of the concession object.

5. The creation (reconstruction) and operation of public health 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.

6. A concession object can be run not only by a concessionaire, but also by a functional operator in the field of healthcare.

In this case, the concessionaire has the right to the reimbursement of costs and receipt of income for the sale of the goods (works, services) produced as part of the maintenance of the concession object.

7. 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 transfers the created concession object under an agreement on the free use of state property to a functional operator in the field of healthcare for the implementation of functional services in the manner specified by the concession agreement;

2) the concessionaire maintains the concession object in the manner and on the conditions provided for by the concession agreement;

3) the functional operator in the field of healthcare, appointed before the tender for the selection of a concessionaire, provides functional services for the concession object in the manner and on the conditions provided for by the concession agreement.

8. 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 in the field of healthcare, as well as the procedure for joint use of the concession object by the concessionaire and the functional operator in the field of healthcare.

9. The functional operator in the field of healthcare shall have permits for such activities provided for by the legislation of the Republic of Kazakhstan or receive them before using the concession object as intended.

10. The functional operator in the field of healthcare can:

1) exercise rights in relation to the concession object on the terms provided for by the agreement on the free use of state property concluded for the purpose of functional maintenance of the concession object;

2) use the concession object together with the concessionaire in the manner and on the conditions provided for by the concession agreement;

3) exercise other rights in accordance with the laws of the Republic of Kazakhstan.

11. The functional operator in the field of healthcare shall:

1) maintain the profile of the concession object;

2) produce goods and (or) perform works, and (or) provide services provided for by the agreement on the free use of state property;

3) comply with the legislation of the Republic of Kazakhstan in the field of labor, public employment and environmental protection;

4) compensate for the damage caused to the concession object through its fault;

5) comply with the conditions 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 agreement on the free use of state property.

12. Under public-private partnership projects of particular importance, involving the creation (reconstruction) and (or) operation of healthcare facilities, including concession projects, the potential private partners, concessionaires or founders (participants) of a new legal entity (consortium) established for the purpose of implementing project, shall be imposed an additional (special) qualification requirement for experience (experience of one of

the founders (participants) in the implementation of projects for the construction or operation of technically complex healthcare facilities.

**Footnote. Article 66 as amended by the Law of the Republic of Kazakhstan dated 02.01.2021 № 399-VI (shall be enforced upon expiration of ten calendar days after the date of its first official publication ); dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication).**

## **Chapter 9. FINANCIAL SUPPORT FOR THE HEALTHCARE SYSTEM**

### **Article 67. Sources of financial support for the healthcare system**

The sources of financial support for the healthcare system are:

- 1) budgetary funds;
- 2) assets of the social health insurance fund;
- 3) voluntary medical insurance funds;
- 4) funds received for the provision of paid services;
- 5) funds received from co-payment;

5-1) lump-sum pension payments of individuals in cases provided for by the laws of the Republic of Kazakhstan;

- 6) funds received as voluntary donations from individuals and legal entities;
- 7) other sources that do not contradict the legislation of the Republic of Kazakhstan.

**Footnote. Article 67 as amended by the Law of the Republic of Kazakhstan dated 02.01.2021 № 399-VI (вводится в действие с 01.01.2021).**

### **Article 68. Financing of medical care volumes**

1. The guaranteed volume of free medical care is financed using:

- 1) budgetary funds;
- 2) funds of citizens in case of co-payment.

2. Medical assistance provided within the compulsory social health insurance system is financed using:

- 1) assets of the social health insurance fund;
- 2) funds of citizens in case of co-payment.

3. Financial support of the additional volume of medical care is provided in accordance with subparagraph 3) of Article 195 of this Code.

### **Article 69. The use of sources of financial support for the healthcare system**

1. Funds in the field of healthcare go to:

- 1) the implementation of programs to strengthen and develop public healthcare;
- 2) the training and advanced training of healthcare personnel;

3) the development and introduction of achievements of medical and pharmaceutical sciences;

4) the payment for services of public health entities within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

4-1) payment for treatment to individuals at the expense of lump-sum pension payments in accordance with the legislation of the Republic of Kazakhstan;

4-2) payment for the services on provision of medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system;

5) the purchase of medicines, medical products, blood and its components, vaccines and other immunobiologicals;

6) ensuring the sanitary-epidemiological welfare of the population;

7) the maintenance of state-run healthcare institutions;

8) material and technical equipment of healthcare organizations;

9) the development of the healthcare infrastructure;

10) cover other expenses not prohibited by the legislation of the Republic of Kazakhstan.

2. The payment for services of public health facilities within the guaranteed volume of free medical care and (or) in the system of compulsory social medical insurance is made with account of the results of the monitoring of contractual obligations for the quality and volume of medical services in the manner prescribed by the authorized body.

2-1. payment for the services of healthcare entities within the additional volume of medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system, shall be carried out subject to the results of monitoring of contractual obligations on quality and volume of medical services in accordance with the procedure, determined by the authorized body.

3. Entities operating in the field of distribution of medicines and medical products are paid for pharmaceutical services provided within the guaranteed volume of free medical care and (or) medical assistance in the system of compulsory social health insurance by budget program administrators or the social health insurance fund in the manner prescribed by the authorized body.

4. The services provided by public health entities within the guaranteed volume of free medical care are purchased by the social health insurance fund and (or) budget program administrators.

The services provided by public health entities in the compulsory social health insurance system are purchased by the social health insurance fund.

4-1. Accounting of the healthcare entities providing medical care within the guaranteed volume of free medical care is carried out by the social health insurance fund.

The database of health care subjects applying for the provision of medical care within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance shall be formed by the Social Health insurance fund.

5. The services provided within a guaranteed volume of free medical care are paid for by the social health insurance fund and (or) budget program administrators.

The services of public health entities provided as part of medical assistance within the compulsory social health insurance system are paid for by the social health insurance fund.

5-1. In order to purchase and pay for the services of healthcare entities within the guaranteed amount of free medical care and (or) in the system of compulsory social medical insurance, the social medical insurance fund combines the funds of the target contribution allocated for the guaranteed amount of free medical care and the assets of the fund.

6. Accredited healthcare organizations have a preferential right to conclude contracts within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance.

**Footnote. Article 69 as amended by the Law of the Republic of Kazakhstan dated 02.01.2021 № 399-VI (shall be enforced from 01.01.2021); dated 24.06.2021 № 52-VII (shall be enforced upon expiration of ten calendar days after the date of its first official publication ) ; dated 30.12.2021 № 95-VII (shall be enforced from 01.07.2022); dated 19.04.2023 № 223-VII (effective from 01.01.2024).**

## **Article 70. National health accounts**

1. National health accounts are a system of regular, comprehensive and consistent monitoring of financial flows in the country's healthcare system, which is used to assess the distribution of healthcare resources with a view to their equal and effective distribution among measures aimed at preventing diseases and treating the population.

2. National health accounts are generated annually on the basis of international methodology using:

- 1) statistical bulletins of the authorized body for state statistics;
- 2) data of the central authorized body for budget execution;
- 3) data of local authorized bodies for budget execution in the context of medical facilities;
- 4) statistical data published on the official websites 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 prepares an analytical report with a description of 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 the formation and use of data from national health accounts is determined by the authorized body.

## **Chapter 10. INTERNATIONAL COOPERATION IN THE FIELD OF HEALTHCARE**

### **Article 71. International cooperation in the field of healthcare**

1. International cooperation in the field of healthcare is carried out on the basis of generally recognized principles and norms of international law and international treaties of the Republic of Kazakhstan.

2. International cooperation includes interaction on health issues with official representatives of states, international organizations and international integration associations, participation in international events, the development of international treaties.

3. Health management bodies, public health entities have the right to establish direct contacts with health management bodies of foreign states, foreign enterprises, institutions and organizations in accordance with the legislation of the Republic of Kazakhstan and international treaties.

4. Agreements, treaties concluded within the framework of international cooperation in the field of healthcare, including those concluded by health management bodies, public health entities, may not restrict human rights and freedoms and those of citizens of the Republic of Kazakhstan in the field of public health protection.

#### **Article 72. Priority areas of international cooperation in the field of healthcare**

The priorities of international cooperation in the field of healthcare are as follows:

1) protection of the interests of citizens of the Republic of Kazakhstan and the interests of the Republic of Kazakhstan in the field of healthcare;

2) participation in international health initiatives;

3) attracting investments and providing technical assistance in the field of healthcare at the interstate level;

4) provision of medical assistance to foreigners, stateless persons;

5) increasing the level of medical assistance by introducing international innovative technologies and modernizing the healthcare system;

6) integration into world medical and pharmaceutical science;

7) assistance in addressing the provision of medical assistance to migrant workers;

8) interstate cooperation on educational activities in the field of healthcare, training and advanced training of medical personnel based on modern achievements of science and practice;

9) provision and receipt of international assistance in the field of healthcare in case of emergencies;

10) exchange of information, technologies with foreign states and international organizations in the field of distribution of medicines, medical products and harmonization of requirements for the safety and quality of pharmaceutical and medical products;

11) sanitary protection of borders in accordance with the requirements of international medical-sanitary rules, ensuring the safety of imported products.

#### **Article 73. Economic and legal basis for international cooperation in the field of healthcare**



1. The economic basis of international cooperation in the field of healthcare is:
  - 1) compulsory and voluntary membership fees to international organizations;
  - 2) attraction and use of grants, technical assistance;
  - 3) financing in accordance with concluded international agreements.
2. The legal basis for international cooperation in the field of healthcare is international treaties.

## **SECTION 2. PUBLIC HEALTH PROTECTION**

### **Chapter 11. GENERAL PROVISIONS OF PUBLIC HEALTH PROTECTION**

#### **Article 74. Priority areas of public health protection**

1. The priority areas of public health protection are as follows:
  - 1) health promotion through the formation of the population's medical-social activity and attitudes towards a healthy lifestyle;
  - 2) raising the level of public awareness about main aspects of health and risk factors;
  - 3) epidemiological surveillance of infectious and priority non-communicable diseases;
  - 4) organization of interaction of all concerned state bodies, organizations and departments, public associations, business communities, and other individuals and legal entities.
2. The public health service is the activity of state bodies, individuals and legal entities, public associations aimed at promoting a healthy lifestyle, healthy diet, assessing the impact of behavioral risk factors on health, preventing infectious and non-communicable diseases.

#### **Article 75. Statistical observation in the field of public health**

1. Health statistics is a branch of statistics that includes statistical data on public health, activities of public health entities and use of healthcare resources.
2. Statistical observation in the field of healthcare is carried out by the authorized body.
3. The procedure for statistical observation in the field of healthcare, the forms of statistical recording and reporting in the field of healthcare, the procedure for their maintenance, filling out and deadlines for submission are established by the authorized body.
4. Statistical health indicators are used for statistical analysis, resource forecasting and modeling of processes in the field of healthcare, health system policy planning, making managerial decisions.
5. Official statistical information in the field of healthcare is publicly available and is posted by the authorized body in the media, including on its official website.

### **Chapter 12. RIGHTS AND OBLIGATIONS OF INDIVIDUALS IN THE FIELD OF HEALTHCARE**

#### **Article 76. Guarantee of rights in the field of healthcare**

1. The state guarantees to citizens of the Republic of Kazakhstan are as follows:

- 1) equal access to medical assistance;
- 2) good quality of medical assistance;
- 3) good quality of drug provision;
- 4) availability, efficacy and safety of medicines;
- 5) carrying out measures for the prevention of diseases, the formation of a healthy lifestyle and healthy nutrition;
- 6) freedom of reproductive choice, protection of reproductive health and observance of reproductive rights;
- 7) sanitary-epidemiological welfare.

2. The Republic of Kazakhstan guarantees the citizens of the Republic of Kazakhstan protection from any forms of discrimination and stigmatization due to the presence of any diseases and conditions.

#### **Article 77. Rights of citizens of the Republic of Kazakhstan**

1. Citizens of the Republic of Kazakhstan have the right to:

- 1) a guaranteed volume of free medical care;
- 2) medicines and medical products within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;
- 3) free choice of a physician and a medical facility;
- 4) medical nutrition in the event of a patient's treatment in a hospital;
- 5) additional medical assistance in excess of the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance at the expense of their own funds , funds of organizations, the system of voluntary medical insurance and other sources in accordance with the legislation of the Republic of Kazakhstan;
- 6) medical and other services on a paid basis;
- 7) medical assistance provided outside the Republic of Kazakhstan at the expense of budgetary funds, given indications, in the manner prescribed by the authorized body;
- 8) the receipt and submission of relevant documents certifying the fact of temporary disability, in accordance with the legislation of the Republic of Kazakhstan;
- 9) free and regular receipt from state bodies, organizations and an attending physician, within their competence, of reliable information on methods of prevention, diagnosis, treatment of the disease and medical rehabilitation, clinical trials, factors affecting health, including the state of the environment, working conditions, life and recreation, healthy diet and food safety;
- 10) receive information from state bodies, independent expert organizations and entities in the field of distribution of medicines and medical products on the safety, efficacy and good quality of medicines and medical products sold;
- 11) the protection of information falling under medical confidentiality;

12) compensation for harm caused to health in the provision of medical assistance in accordance with the legislation of the Republic of Kazakhstan;

13) protect their rights and legitimate interests in the field of health protection in accordance with the legislation of the Republic of Kazakhstan;

14) appeal against actions (inaction) of healthcare professionals and pharmaceutical workers in the manner prescribed by the laws of the Republic of Kazakhstan;

15) petition higher authorities for involving independent experts in case of disagreement with the findings of state medical examination;

16) voluntary declaration of will about the opportunity to act as a donor;

17) declaration of will of consent or refusal to remove their tissues (parts of tissue) and (or) organs (parts of an organ) after death for the purpose of transplantation in the manner prescribed by this Code;

18) give informed consent or refusal for treatment and other medical interventions, including preventive vaccinations;

19) co-payment;

20) pain relief in the treatment of chronic incurable diseases;

21) get information in an intelligible form on the state of health, including information on the results of medical examination, diagnosis and prognosis of the disease, methods of providing medical care, associated risk, possible types of medical intervention, its consequences and the results of providing medical assistance;

22) get reliable and timely information on factors that contribute to the preservation of health or have a negative impact on them, including information on the prevention of diseases, sanitary-epidemiological welfare, the state of the environment, the potential danger to human health from the work performed and services provided, rational nutritional standards, quality and safety of products, goods and services;

23) other rights in accordance with the laws of the Republic of Kazakhstan.

1-1. Persons with disabilities (persons with disabilities) have the right to priority care in healthcare organizations.

2. Women have the right to decide on their motherhood and free choice of modern methods of preventing unwanted pregnancy for the purposes of family planning and protecting their health.

The right of citizens to maternity protection is exercised through:

1) medical examinations, dynamic observation and health improvement of women of reproductive age;

2) medical treatment of common diseases that directly affect the reproductive health of women and the health of the child when admitted to a hospital for the care of a sick child.

**Footnote. Article 77 as amended by the Law of the Republic of Kazakhstan dated 27.06.2022 № 129-VII (shall be enforced ten calendar days after the date of its first official publication).**

## **Article 78. Children's rights**

1. In addition to the rights provided for in paragraph 1 of Article 77 of this Code, every child has the right to:

- 1) modern and effective medical services and means of treating diseases and health recovery;
- 2) education in the field of health protection;
- 3) preventive medical examinations and dynamic observation, treatment, drug provision, health improvement and vaccination;
- 4) the provision of medical services during the recovery period and organized recreation in the manner prescribed by the authorized body;
- 5) sanitary and hygienic education, training and work under conditions appropriate for his /her physiological characteristics and state of health, excluding the influence of adverse factors on him/her;
- 6) obtain medical documentation on the state of health on a free basis at the place of his/her registration when becoming a student and being employed;
- 7) obtain information on the state of health in an intelligible form;
- 8) obtain information in an intelligible form on a healthy lifestyle and proper nutrition, on the dangers of smoking, the use of psychoactive substances;
- 9) obtain information in an intelligible form on the protection of reproductive health;
- 10) palliative care.

2. Minors aged sixteen and over have the right to informed consent or refusal to preventive, consultative and diagnostic assistance, except for surgical interventions, artificial abortion, which are performed with the consent of their parents or legal representatives.

3. When treating children under five years of age in a hospital, as well as sick older children who, in doctors' opinion, need additional care, the mother (father) or another person directly caring for the child is given the opportunity to stay with him/her in the medical facility and a sheet or certificate of temporary disability in accordance with the legislation of the Republic of Kazakhstan.

A nursing mother of a child up to one year of age is provided with free meals by a medical facility for the entire period of childcare.

4. When treating children under five years of age in outpatient and hospital-replacing conditions, as well as sick older children who, in doctors' opinion, need additional care, the mother (father) or another person directly caring for the child is given the opportunity to stay with him/her and a sheet or certificate of temporary disability in accordance with the legislation of the Republic of Kazakhstan.

5. When receiving specialized medical assistance, medical rehabilitation, as well as palliative medical care in stationary conditions, school-age children have the right to continue

education in the manner prescribed by the authorized body together with the authorized body for education.

Healthcare organizations providing medical assistance to children create conditions for their games, recreation and education.

6. Children with disabilities, infected with HIV have the right to receive free medical-pedagogical correctional support in educational institutions, healthcare organizations in accordance with the legislation of the Republic of Kazakhstan.

Children infected with HIV have the right to stay in children's homes and other healthcare organizations and educational institutions.

Children born to mothers infected with HIV have the right to receive free adapted milk formulas in accordance with established nutritional standards.

6-1. Children with disabilities (children with disabilities) have the right to priority care in healthcare organizations.

7. The list of medical contraindications for placing children in a children's home and educational institutions, organizations for orphans and children left without parental care is approved by the authorized body.

8. Orphans, children left without parental care, and children who are recipients of special social services, until they reach the age of three years inclusive, may be kept in state medical organizations in accordance with the procedure established by the authorized body.

**Footnote. Article 78 as amended by the Law of the Republic of Kazakhstan dated 27.06.2022 № 129-VII (shall be enforced ten calendar days after the date of its first official publication); dated 20.04.2023 № 226-VII (shall be enforced from 01.07.2023).**

## **Article 79. Rights of citizens of the Republic of Kazakhstan and a family in the field of protection of reproductive rights**

1. Citizens of the Republic of Kazakhstan have the right to:
  - 1) free reproductive choice;
  - 2) receive services for reproductive health and family planning;
  - 3) get reliable and complete information on the state of their reproductive health;
  - 4) infertility treatment, also with the use of modern assisted reproductive methods and technologies, which are permitted in the Republic of Kazakhstan;
  - 5) prevent unwanted pregnancy;
  - 6) safe motherhood;
  - 7) the donation of germ cells, tissue of reproductive organs;
  - 8) the use and free choice of contraception methods;
  - 9) surgical sterilization;
  - 10) artificial abortion;
  - 11) protect their reproductive rights;

12) free decision-making regarding the number of children and the time of their birth within and out of wedlock, the intervals between births necessary to maintain the health of the mother and child;

13) store germ cells, tissue of reproductive organs, embryos in accordance with the procedure established by the legislation of the Republic of Kazakhstan.

2. When exercising their reproductive rights, citizens are obliged to observe the rights, freedoms and legal interests of other persons.

3. Given medical indications, citizens have the right to consultations on family planning, the presence of socially significant diseases and diseases that pose a danger to others, on the medical and psychological aspects of family and marriage relations, as well as to medical genetic and other consultations and examinations in medical facilities in order to prevent possible hereditary and congenital diseases in descendants.

4. The child's father or another family member is granted the right, given the woman's consent and taking into account the state of her health, to be present at the birth of the child, except for cases of operative delivery, provided that obstetrics organizations (individual delivery rooms) have appropriate conditions and the father or another family member has no infectious diseases. This right is exercised free of charge.

5. HIV-infected citizens of the Republic of Kazakhstan have the right to adopt children on an equal basis with other citizens of the Republic of Kazakhstan in accordance with the legislation of the Republic of Kazakhstan.

6. HIV-infected citizens of the Republic of Kazakhstan have the right to use assisted reproductive methods and technologies in accordance with the legislation of the Republic of Kazakhstan.

#### **Article 80. Obligations of citizens of the Republic of Kazakhstan**

Citizens of the Republic of Kazakhstan are obliged to:

1) take care of their health, bear joint responsibility for the preservation and strengthening of individual and public health;

2) pay contributions for compulsory social health insurance in accordance with the Law of the Republic of Kazakhstan "On Compulsory Social Health Insurance";

3) take preventive medical examinations, screening tests;

4) follow the prescriptions of healthcare professionals related to individual and public health;

5) take part in the process of managing their own health, including in programs for managing chronic diseases, if any, be interested in getting information on the disease and methods of its treatment, possible risks and complications;

6) inform healthcare professionals on individual characteristics of their body;

7) observe precautions to protect their own health and the health of others, take examination and treatment at the request of public health entities, inform medical personnel on the presence of infectious and other diseases that pose a danger to others;

8) comply with the legislation of the Republic of Kazakhstan in the field of healthcare.

In case of evasion of examination and treatment, citizens of the Republic of Kazakhstan, sick with diseases that pose a danger to others, except for HIV infection, are subject to forcible examination and treatment in accordance with this Code and the laws of the Republic of Kazakhstan.

### **Article 81. Rights and obligations of pregnant women and mothers in the field of health protection**

1. Motherhood in the Republic of Kazakhstan is protected and encouraged by the state.

2. Citizens have the right to support breastfeeding, including protection and promotion of breastfeeding, inter alia:

1) the protection of the rights of pregnant and nursing women is aimed at ensuring conditions for the preparation and implementation of breastfeeding (maternity leave, additional breaks from work to feed infants, part-time work, services on a priority basis in medical facilities, use of the services provided by parenting rooms, etc.);

2) informing the population on the benefits of exclusive breastfeeding for children under six months of age and on continuing breastfeeding with healthy complementary foods for up to two years or more.

3. Pregnant women have the right to:

1) health protection and assistance during pregnancy, during and after childbirth, including premature one, determined by the international live birth and stillbirth criteria, using methods permitted in the Republic of Kazakhstan;

2) medical assistance during pregnancy, during and after childbirth;

3) examination, treatment and medical intervention during pregnancy only with their consent or that of a legal representative, except for cases when delay in examination, treatment and medical intervention threatens the life of a woman and a child (fetus), when a decision to carry out examination, treatment and medical intervention is made by a doctor or a medical case conference;

4) observe a work schedule, maternity leave, unpaid leave to care for a child until the child reaches the age of three, and working conditions for pregnant women and nursing mothers in accordance with the labor legislation of the Republic of Kazakhstan;

5) qualified support provided to nursing mothers (parents), counseling by healthcare professionals trained in lactation, methods of exclusive breastfeeding and complementary feeding;

6) support for the practice of breastfeeding, which is implemented by child-friendly medical facilities;

7) time for medical examination and registration as pregnant within twelve weeks of gestation, which is granted by an employer together with protecting job, securing position and preserving average salary;

8) other guarantees and incentives in accordance with the laws of the Republic of Kazakhstan.

4. Pregnant women are obliged to:

1) within twelve weeks of gestation, register as pregnant at the place of registration for receiving medical assistance within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

2) follow the doctor's recommendations during pregnancy, during and after childbirth.

5. If a woman with contraindications for pregnancy plans a pregnancy, she assumes full responsibility for all health risks to herself and the fetus during pregnancy and up to forty-two calendar days of childbirth.

#### **Article 82. Obligations of individual entrepreneurs and legal entities for their employees' health protection**

1. In accordance with their activities, individual entrepreneurs and legal entities are obliged:

1) to take sanitary-antiepidemic and sanitary-preventive measures;

2) to comply with regulatory legal acts in the field of sanitary-epidemiological welfare of the population, as well as acts of officials exercising state control and supervision in the field of sanitary-epidemiological welfare of the population;

3) to ensure the safety and good quality of works performed, services provided and products during their production, transportation, storage and sale to the population, disposal and destruction;

4) to perform production control;

5) to promptly inform the state body for the sanitary-epidemiological welfare of the population on emergencies, suspension of production, breakdowns in technological processes that pose a threat to the sanitary-epidemiological welfare of the population, in cases of mass and group infectious and parasitic, occupational diseases and poisoning;

6) to promptly inform the state body for the distribution of medicines and medical products on the identification of side effects of medicines and medical products;

7) to arrange hygienic training for employees belonging to the decreed population group;

8) to provide officials of the state body for the sanitary-epidemiological welfare of the population with the opportunity to take samples of products, raw materials, goods, production environment for laboratory research within their competence;

9) to bar from working persons without a document certifying their medical examination, hygienic training, and also those with infectious, parasitic diseases and carriers of pathogens of infectious, parasitic diseases, persons with contraindications to work in harmful and (or)



hazardous working conditions identified by public health entities, except for those infected with HIV;

10) to prohibit the sale of goods, products, raw materials which are found to be inconsistent with regulatory legal acts in the field of sanitary-epidemiological welfare of the population, and also to make a decision on the possibility of their use or disposal;

11) to submit accounting and reporting documentation relating to the sanitary-epidemiological welfare of the population for inspection to the state body for the sanitary-epidemiological welfare of the population;

12) to suspend entrepreneurial and (or) other activities if they pose a threat to the life or health of the population;

13) to ensure unhindered access of officials exercising state control and supervision in the field of sanitary-epidemiological welfare of the population to facilities in order to check their compliance with regulatory legal acts in the field of sanitary-epidemiological welfare of the population;

14) at their own expense, to carry out disinfection, disinsection and deratization according to epidemiological indications and prescriptions, decisions of officials of the state body for the sanitary-epidemiological welfare of the population;

15) to pay deductions and (or) contributions for compulsory social health insurance in accordance with the Law of the Republic of Kazakhstan “On Compulsory Social Health Insurance”.

2. The employer shall create favorable conditions for health promotion and disease prevention among employees.

### **Article 83. Rights and obligations of kandasses, foreigners, stateless persons and other persons**

1. Kandasses, refugees, as well as foreigners and stateless persons permanently residing in the Republic of Kazakhstan, have the right to receive a guaranteed volume of free medical care on an equal basis with citizens of the Republic of Kazakhstan.

2. Foreigners and stateless persons temporarily staying in the Republic of Kazakhstan, asylum seekers have the right to receive a guaranteed volume of free medical care for diseases that pose a danger to others, according to the list and in the amount determined by the authorized body unless otherwise provided for by laws of the Republic of Kazakhstan or international treaties ratified by the Republic of Kazakhstan.

Foreigners and stateless persons identified as victims of human trafficking in the territory of the Republic of Kazakhstan have the right to receive a guaranteed amount of free medical care according to the list and in the amount determined by the authorized body.

3. Kandasses, refugees and asylum seekers, foreigners and stateless persons staying in the Republic of Kazakhstan bear the same responsibilities in the field of healthcare as the citizens of the Republic of Kazakhstan.

Footnote. Article 83 as amended by the Law of the Republic of Kazakhstan dated 27.06.2022 № 129-VII (shall be enforced ten calendar days after the date of its first official publication).

## **Chapter 13. FEATURES OF THE PUBLIC HEALTH PROTECTION**

### **Article 84. Prevention of diseases and formation of a healthy lifestyle**

1. The purpose of disease prevention is to prevent the emergence or progression of diseases, as well as their consequences and complications.

2. Disease prevention can be primary, secondary and tertiary.

Primary prevention of diseases (mass and individual) is aimed at creating favorable conditions for life in order to prevent the emergence of diseases.

Secondary prevention of diseases is aimed at preventing the progression of diseases in the early stages and their consequences.

Tertiary prevention of diseases is aimed at controlling the already developed complications, damage to organs and tissues.

3. Preventive and health-improving measures are carried out in relation to all groups of the population throughout life and take into account gender, age, psychological and social aspects.

4. The formation of a healthy lifestyle includes regular exercise, promotion of a healthy lifestyle, healthy nutrition and disease prevention through information support, hygienic education and education of the population in promoting health and preventing diseases associated with a lifestyle.

Physical exercises in organizations are carried out on weekdays.

Standard rules for making physical exercises are developed and approved by the authorized body.

### **Article 85. Prophylactic immunization**

1. Prophylactic immunization is the administration of immunobiologicals to the human body for immunoprophylaxis in order to create a specific immunity to infectious diseases.

2. Prophylactic immunization can be mandatory and voluntary.

3. There are such types of mandatory prophylactic immunization as:

1) planned prophylactic immunization;

2) prophylactic immunization given epidemiological indications.

4. Individuals permanently residing in the Republic of Kazakhstan are subject to mandatory prophylactic immunization against infectious and parasitic diseases.

5. The list of diseases requiring mandatory prophylactic immunization within the guaranteed volume of medical care, the procedure, timing of their implementation and

population groups subject to prophylactic immunization are determined by the Government of the Republic of Kazakhstan.

6. Persons who have reached the age specified in the list of diseases requiring mandatory prophylactic immunization and not having medical contraindications are subject to planned prophylactic immunization.

7. Before the prophylactic immunization, a healthcare professional examines a person to be immunized. The healthcare professional provides him/her or his/her legal representative with complete and objective information on prophylactic immunization, possible adverse events and consequences of refusing it.

The list of medical contraindications for prophylactic immunization is approved by the authorized body.

8. Individuals without medical contraindications are subject to prophylactic immunization given epidemiological indications according to the list.

9. Prophylactic immunization not included in the list of diseases requiring mandatory prophylactic immunization is voluntary and is carried out on a paid basis.

10. The procedure for registering and investigating adverse events following immunization is established by the authorized body.

11. Children who have not received routine preventive vaccinations are admitted to preschool institutions only when the threshold level of herd immunity in the preschool institution is achieved.

Herd immunity is indirect protection of unvaccinated persons ensured by achieving the threshold level of coverage with routine preventive vaccinations of the population against vaccine-preventable infections.

The rules for admitting children without routine preventive vaccinations to preschool institutions and the threshold level of herd immunity are determined by the authorized body.

## **Article 86. Medical examination**

1. A medical examination is carried out to ensure a timely medical check-up aimed at identifying and preventing the spread of diseases, including occupational diseases, poisoning, accidents, and also to ensure occupational safety and health protection of employees.

2. The types of medical examinations are mandatory and preventive.

3. Mandatory medical examinations are subdivided into preliminary, periodic, pre-shift (pre-trip), post-shift (post-trip) ones.

Preliminary mandatory medical examinations are carried out when admitting to work or study in order to ascertain the suitability for performing professional duties or study, and also to prevent general, occupational diseases and the spread of infectious and parasitic diseases.

Periodic mandatory medical examinations are carried out in order to ensure dynamic observation of the health status of workers, timely identify initial signs of diseases, and prevent general, occupational diseases and the spread of infectious and parasitic diseases.

Pre-shift (pre-trip) mandatory medical examinations are carried out in order to identify or confirm the presence or absence of a disease in an individual, to determine the state of health, as well as temporary disability, professional suitability for work in the oncoming shift (trip), including the influence of alcohol, drugs or other toxicants, and the residual effects of such intoxication.

Post-shift (post-trip) medical examinations are carried out at the end of a working day (shift, trip) in order to identify signs of the impact of harmful and (or) hazardous production factors of the working environment and the labor process on the health of workers, acute occupational disease or poisoning, signs of alcohol, drug or other toxicants.

4. The list of harmful and (or) hazardous production factors, professions and jobs, the performance of which requires preliminary mandatory medical examinations before the admission to work and periodic mandatory medical examinations, is approved by the authorized body.

5. Employers, at their own expense, arrange for timely pre-shift (pre-trip), post-shift (post-trip) mandatory medical examinations for employees engaged in heavy work, work in harmful and (or) dangerous working conditions, machines and mechanisms in accordance with the legislation of the Republic of Kazakhstan in the field of healthcare.

The decreed group of the population takes mandatory medical examinations at their own expense or at the expense of the employer by agreement of the parties.

6. Target groups of persons subject to mandatory medical examinations, as well as their procedure and frequency, the volume of laboratory and functional tests, medical contraindications are determined by the authorized body.

7. Employers create conditions for employees to take medical examinations and are also obliged, without hindrance, to grant them a paid leave to take them.

8. Employers do not admit to work persons who failed to take mandatory medical examinations and those recognized as unfit for work for health reasons. The results of mandatory medical examinations are entered into personal medical history sheets.

9. The procedure for issuing, recording and maintaining personal medical history sheets is determined by the state body for the sanitary-epidemiological welfare of the population.

10. Preventive medical examinations are carried out among the child population and include a set of medical and other measures aimed at preventing the emergence of diseases and their early diagnosis, followed by dynamic observation and rehabilitation.

11. The rules, volume and frequency of preventive medical examinations of target population groups, including children of preschool, school age, as well as students of technical and vocational, post-secondary and higher educational institutions, are developed and approved by the authorized body.

12. Timeliness, quality of conducting and taking preventive and mandatory medical examinations are controlled by the state body for the sanitary-epidemiological welfare of the population.

## **Article 87. Screening**

1. Screening is carried out among target groups of the population in order to identify diseases in their early stages and prevent the development of diseases, risk factors that contribute to the emergence of diseases, to form and improve public health.

2. Target groups of persons subject to screening shall be screened in the manner, to the extent and as frequently as determined by the authorized body.

3. The screening results are entered into an electronic health passport by public health entities doing the screening.

4. Employers create conditions for persons subject to the screening to have it done within the framework of the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance, and also, without hindrance, grant a paid leave to employees for the screening during working hours in accordance with the labor legislation of the Republic of Kazakhstan.

5. The timeliness and quality of screening are controlled by the state body for medical services (assistance).

## **Article 88. Dynamic observation**

1. Patients with chronic diseases are subject to dynamic observation within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance.

2. The list of chronic diseases subject to dynamic observation is approved by the authorized body.

3. The rules for providing medical services to persons with chronic diseases, the frequency and timing of observation, the mandatory minimum and frequency of diagnostic tests are approved by the authorized body.

## **Article 89. Temporary disability examination**

1. Temporary disability examination is done in order to officially recognize the disability of an individual and his/her temporary release from work duties for the period of illness.

2. The procedure for the examination of temporary disability for work, as well as the issuance of a sheet or certificate of temporary disability for work, shall be established by the authorized body.

## **Article 90. First aid**

1. First aid is a set of basic urgent measures to save a person's life, prevent complications in emergency conditions, and also to reduce the threat to the health and life of an injured person in an emergency, which are taken at the scene by the victim himself/herself (self-help) or another nearby person (mutual assistance) before healthcare professionals arrive.

First aid can be provided by persons without medical education, including those appropriately trained, in the manner prescribed by the authorized body.

2. Certified trainers for teaching citizens of the Republic of Kazakhstan to acquire first aid skills are trained by public health entities that meet the requirements set by the authorized body.

3. The list of professions with an indication of the contingent of employees who are obliged to take first aid courses, as well as their frequency, are approved by the authorized body jointly with the concerned state bodies.

4. The rules for training citizens of the Republic of Kazakhstan in the first aid skills, as well as the list of emergency and urgent conditions for providing first aid, are developed and approved by the authorized body.

5. Training in the first aid skills is carried out using budgetary funds, employer's funds or own funds of citizens of the Republic of Kazakhstan.

6. The first aid standard is developed and approved by the authorized body.

#### **Article 91. Preschool and school medicine**

1. The activities of preschool and school medicine are aimed at health protection and dynamic observation of the health status of pupils and schoolchildren.

2. Measures to protect the health of pupils and schoolchildren include:

1) preventive medical examinations right in preschool and educational institutions, also with the involvement of mobile teams of specialists;

2) recreational activities during the academic period and holidays;

3) introduction of health-saving technologies in preschool and secondary educational institutions aimed at preventing diseases, introduction and observance of the principles of rational nutrition, protection of reproductive health;

4) protection of mental health, prevention of suicidal behavior and addictions caused by the consumption of tobacco products, non-medical use of psychoactive substances, as well as pathological gambling;

5) referral of schoolchildren for an in-depth medical examination following the results of preventive examinations;

6) immunization according to the National Vaccination Schedule;

7) organization and conduct of training seminars, training courses and lectures on disease prevention, promotion and formation of a healthy lifestyle among schoolchildren, first aid;

8) involvement of parents and teachers in the protection of health of pupils and schoolchildren through educational and awareness-raising activities;

9) compliance with the requirements of sanitary rules;

10) provision of first aid in case of emergency conditions before the arrival of healthcare professionals providing emergency medical assistance.

3. Medical assistance to pupils and schoolchildren is arranged for by public health entities providing primary health services in the territory of location of preschool and secondary (primary, basic secondary, general secondary) educational institutions.

4. The organization of the activities of preschool and school medicine is carried out by local public health authorities.

### **Article 92. Features of providing reproductive and mental health services to minors aged 10-18 and young people**

1. Healthcare entities provide minors aged 10-18 and young people with confidential comprehensive assistance, including medical, psychosocial and legal services.

2. Minors aged 10-18 and young people are accessed to services and means of protection of reproductive and mental health without a referral from primary healthcare specialists.

3. The rules for organizing medical assistance for the protection of the reproductive and mental health of minors aged 10-18 and young people are developed and approved by the authorized body.

## **Chapter 14. ACTIVITIES IN THE FIELD OF SANITARY-EPIDEMIOLOGICAL WELFARE OF THE POPULATION**

### **Article 93. The system of the sanitary-epidemiological service**

The unified system of the state sanitary-epidemiological service includes:

1) the state body for the sanitary-epidemiological welfare of the population and its territorial units;

2) structural units of other state bodies carrying out activities in the field of sanitary-epidemiological welfare of the population;

3) legal entities and individuals carrying out activities in the field of sanitary-epidemiological welfare of the population.

### **Article 94. State sanitary-epidemiological regulation**

1. State sanitary-epidemiological regulation is the activity of the sanitary-epidemiological service, which includes:

1) the development of uniform requirements for the justification of documents of sanitary-epidemiological regulation and control over their development;

2) the development (processing), examination, approval and publication of documents of sanitary-epidemiological regulation;

3) the study, generalization of the practice of application, control over the application of documents of sanitary-epidemiological regulation;

4) the formation and maintenance of a unified data bank of documents of sanitary-epidemiological regulation;

5) the harmonization of documents of sanitary-epidemiological regulation with generally accepted international requirements.

2. The documents of the state system of sanitary-epidemiological regulation are sanitary rules, hygienic standards, technical regulations, unified sanitary-epidemiological and hygienic requirements for goods of the Eurasian Economic Union, instructions, methodological recommendations, guidelines, techniques, orders, rules and standards.

3. The procedure for the development and approval of documents of the state system of sanitary-epidemiological regulation is determined by the state body for the sanitary-epidemiological welfare of the population.

4. Regulatory legal acts in the field of sanitary-epidemiological welfare of the population include sanitary rules, hygienic standards, rules, technical regulations and uniform sanitary-epidemiological and hygienic requirements for goods of the Eurasian Economic Union.

5. When developing and approving regulatory legal acts concerning issues in the field of the sanitary-epidemiological welfare of the population, state bodies are obliged to have them approved by the state body for the sanitary-epidemiological welfare of the population.

6. Regulatory legal acts in the field of sanitary and epidemiological welfare of the population and documents of the state system of sanitary and epidemiological regulation, containing requirements for handling of pathogenic biological agents are developed and applied taking into account the requirements in the field of biological safety.

**Footnote. Article 94 as amended by the Law of the Republic of Kazakhstan dated 21.05.2022 № 123-VII (shall be enforced six months after the date of its first official publication).**

## **Article 95. Sanitary-epidemiological requirements**

1. Sanitary rules set sanitary-epidemiological requirements for facilities that are subject to state control and supervision in the field of sanitary-epidemiological welfare of the population and contain requirements for:

- 1) the choice of a land plot for the construction of a facility;
- 2) the design, construction of new facilities, reconstruction, re-equipment, redevelopment and expansion of existing facilities, repair and commissioning of facilities;
- 3) the maintenance and operation of industrial, public, residential and other premises, buildings, structures, equipment, vehicles;
- 4) water supply, sewerage, heat supply, lighting, ventilation, air conditioning of facilities;
- 5) the acceptance, storage, processing of raw materials;
- 6) the conditions of production, packaging, transportation, storage, sale, disposal of food products, disposal of tobacco products;
- 7) the conditions for the production, packaging, transportation, storage, sale, disposal and destruction of immunologic agents (immunobiologicals);



8) application and use of potentially dangerous 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), their disposal (destruction), transportation, storage, burial and working conditions with them;

9) the conditions of handling sources of physical factors that affect a person;

10) the conditions for the industrial production of medicines;

11) industrial-technical products;

12) household-hygienic goods and technologies for their production, utilization and destruction;

13) the conditions of upbringing, training, living and industrial practice, physical development, work, rest, food, water supply and medical services for various groups of the population;

14) teaching-work load and the mode of training in educational institutions;

15) the conditions for sterilization and disinfection of medical products;

16) arranging for specialized (children's, dietary therapeutic and dietary preventive), therapeutic and prophylactic, public catering of the population;

17) water sources (places of water intake for household and drinking purposes), household and drinking water supply, and places of cultural and household water use, and safety of water bodies;

18) the collection, use, application, neutralization, transportation, storage and disposal of production and consumption waste;

19) the organization and implementation of works and services, including the development, testing, manufacturing, production, storage, transportation, sale, use of disinfectants, disinsection and deratization agents, equipment, materials, maintenance and operation of objects of disinfection activities, as well as monitoring the effectiveness and safety of works and services;

20) the conditions of passenger transportation;

21) the liquidation, temporary closing-down, conversion of facilities;

22) the implementation of production control;

23) the conditions of labor, consumer services, medical support, specialized dietary therapeutic and dietary preventive nutrition;

24) hygienic education and training of the population;

25) the organization and conduct of sanitary-antiepidemic and sanitary-preventive measures, including the implementation of sanitary protection of the Republic of Kazakhstan, the introduction of restrictive measures, including quarantine, in relation to patients with infectious and parasitic diseases, medical examinations, preventive vaccinations of the population;

26) zones of sanitary protection and buffer zones, roadside clear zones;

27) optimal noise levels at workplaces, permissible noise levels in residential and public buildings and in the area of residential development;

28) the organization and conduct of the population's immunization, the investigation of cases of adverse events following immunization;

29) the organization and implementation of disinfection, disinsection and deratization in natural foci of infectious diseases, as well as in foci of infectious diseases.

2. Hygienic standards set standards for maximum permissible concentrations of harmful (chemical, biological) substances, physical effects, permissible levels of radiation exposure, the observance of which ensures favorable living and safe-health conditions for humans.

3. Hygienic standards are set for:

1) microclimate, air exchange, workplace air, physical factors of industrial, residential and other premises, industrial areas;

2) radiation, chemical, microbiological, toxicological, parasitological safety of products (goods) and the environment;

3) atmospheric air in urban and rural settlements, in the premises of industrial facilities;

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 95 as amended by the Law of the Republic of Kazakhstan dated 21.05.2022 № 123-VII (shall be enforced six months after the date of its first official publication).**

#### **Article 95-1. Collections of pathogenic and industrial microorganisms**

Collection, identification, study, registration, certification, storage (deposit) and maintenance of national and working collections of pathogenic and industrial microorganisms used in the field of sanitary and epidemiological welfare of the population are carried out taking into account the legislation of the Republic of Kazakhstan in the field of biological safety.

**Footnote. Chapter 14 is supplemented by Article 95-1 in accordance with the Law of the Republic of Kazakhstan dated 21.05.2022 № 123-VII (shall be enforced six months after the date of its first official publication).**

### **Chapter 15. PREVENTION OF INFECTIOUS AND NON-COMMUNICABLE DISEASES**

#### **Clause 1. Prevention of infectious diseases**

#### **Article 96. Hygienic training of the population**

1. Hygienic training for the decreed population group is the training in the prevention of infectious and parasitic, occupational diseases, regulatory legal acts in the field of the

sanitary-epidemiological welfare of the population (maintenance, operation and placement of facilities, personal and public hygiene) in accordance with the professions of students.

The list of the decreed population group subject to hygienic training is determined by the state body for the sanitary-epidemiological welfare of the population.

2. Hygienic training is paid for by the decreed persons independently or by their employers by agreement of the parties.

3. Control over the quality of hygienic training for the decreed population group is carried out by the bodies of the state sanitary-epidemiological service by way of:

- 1) monitoring notices of commencement and termination of business;
- 2) checking the compliance with the hygiene training procedure and program;
- 3) checking the knowledge of persons belonging to the decreed group during inspections, preventive control.

#### **Article 97. Requirements for persons carrying out hygienic-training activities**

1. Activities on hygienic training of decreed groups of the population are carried out by individuals or representatives of legal entities with higher education in sanitary-hygienic (medical-preventive) specialty.

2. Individuals and legal entities, before and after the termination of hygienic training activities, are obliged to notify the territorial unit of the state body for the sanitary-epidemiological welfare of the population in accordance with the procedure established by the Law of the Republic of Kazakhstan “On Permits and Notifications”.

3. Persons carrying out hygienic-training activities shall:

- 1) ensure high-quality training;
- 2) comply with regulatory legal acts in the field of sanitary-epidemiological welfare of the population;
- 3) conduct training on the basis of documents of state sanitary-epidemiological regulation in accordance with training programs corresponding to the professions of decreed population groups;
- 4) comply with the hygienic training procedure;
- 5) not allow joint hygienic training of various decreed population groups.

#### **Article 98. Prevention of tuberculosis**

1. Measures for the prevention of tuberculosis are carried out by:

- 1) conducting epidemiological surveillance of the prevalence of tuberculosis among the population;
- 2) specific prophylaxis, including vaccination according to the National Vaccination Schedule;
- 3) early identification of tuberculosis;

- 4) treating active tuberculosis and latent tuberculosis infection;
  - 5) taking a set of infection control measures aimed at preventing the transmission of the tuberculosis pathogen through the ambient air in the habitable environment;
  - 6) social prevention, i.e. improving the living conditions of the population and the quality of food; combating non-medical use of psychoactive substances, smoking; instilling in the population the skills of personal hygiene in everyday life; promotion of physical culture and sports;
  - 7) informing the population through the mass media on the tuberculosis epidemic and preventive measures;
  - 8) developing and disseminating information materials on the prevention of tuberculosis for various groups of the population, also through social networks and the media;
  - 9) placing and implementing state social grants and state social orders through non-governmental organizations.
2. Measures for the tuberculosis prevention are taken in the manner prescribed by the authorized body.

#### **Article 99. Prevention of HIV infection**

1. Measures to prevent HIV infection are taken by:
  - 1) conducting epidemiological monitoring of the prevalence of HIV infection among the population, including key population groups;
  - 2) informing various groups of the population on HIV infection through information materials, social networks and the media;
  - 3) integrating HIV prevention issues into the education system and workplaces;
  - 4) providing key population groups with treatment and prophylactic services in trust points, friendly offices.

A friendly office is a specially organized point for the provision of preventive, therapeutic and diagnostic assistance in case of sexually transmitted infections to HIV-infected people and key population groups on a free basis following the principles of voluntariness and confidentiality;

  - 5) placing and implementing state social grants and state social orders through non-governmental organizations;
  - 6) ensuring the infectious safety of donation and transplantation, as well as when providing the population with services related to the violation of the integrity of the skin and mucous membranes;
  - 7) preventing transmission of HIV infection from a mother to her fetus and child;
  - 8) providing pre-exposure and post-exposure prophylaxis;
  - 9) providing antiretroviral therapy to reduce the risk of HIV transmission from the time of its diagnosing.

2. Measures to prevent HIV infection are taken in the manner prescribed by the authorized body.

#### **Article 100. Medical waste management**

1. Medical waste is a type of production and consumption waste generated during the provision of medical services and medical procedures.

2. According to the level of hazard, medical waste is divided into 5 hazard classes:

1) class A - non-hazardous medical waste, similar to solid household waste;

2) class B - (epidemiologically) hazardous medical waste;

3) class C - extremely (epidemiologically) hazardous medical waste;

4) class D - toxicologically hazardous medical waste, the composition of which is close to industrial waste;

5) class E - radioactive medical waste.

Medical waste of classes B - E is hazardous.

3. Sanitary-epidemiological requirements for the collection, transportation, storage, neutralization, use of medical waste are determined by the sanitary rules approved by the state body for the sanitary-epidemiological welfare of the population.

4. In accordance with the environmental legislation of the Republic of Kazakhstan, waste owners provide the authorized body for environmental protection with information in the form of an annual report in the field of medical waste management (hereinafter referred to as the report) for entering it into the State cadaster of production and consumption waste.

5. Information on medical waste is provided on an annual basis as of January 1, on or before March 1 of a year following a reporting year, in electronic and (or) paper-based form.

6. Waste owners ensure the completeness, continuity and reliability of these reports.

7. The procedure for providing information on medical waste is determined by the state body for the sanitary-epidemiological welfare of the population.

#### **Article 101. Requirements for persons engaged in the collection, transportation, storage, neutralization, burial and (or) use of medical waste**

1. Activities on the collection, transportation, storage, neutralization, use of medical waste are carried out by individuals and legal entities.

2. Individuals and legal entities carrying out activities on the collection, transportation, storage, neutralization, disposal and use of medical waste, prior to the commencement of activities, shall obtain permits in the manner prescribed by the legislation of the Republic of Kazakhstan on permits and notifications.

3. Qualification requirements for individuals and legal entities engaged in the collection, transportation, storage, neutralization, burial and use of medical waste are established by the state body for the sanitary-epidemiological welfare of the population.

## **Article 102. Sanitary-antiepidemic, sanitary-preventive measures**

1. In order to prevent the emergence and spread of infectious and parasitic diseases, poisoning of the population, it is necessary to take sanitary-antiepidemic, sanitary-preventive measures, including sanitary protection of the territory of the Republic of Kazakhstan, the introduction of restrictive measures, including quarantine, in relation to persons with infectious and parasitic diseases, for medical examinations, preventive vaccinations, hygienic training of persons belonging to the decreed group of the population, and persons employed in heavy work, work in harmful and (or) dangerous working conditions.

2. Sanitary-antiepidemic, sanitary-preventive measures shall be included in the documents of the State Planning System of the Republic of Kazakhstan under development.

3. Persons with infectious and parasitic diseases, as well as those with suspected infectious and parasitic diseases, bacteria carriers are subject to isolation and (or) treatment, and persons who were in contact with them - to medical supervision and, if necessary, isolation and (or) treatment.

4. Persons with chronic infectious and parasitic diseases (except for those with HIV infection), chronic bacteria carriers posing a danger to others are subject to temporary suspension from work in accordance with the labor legislation of the Republic of Kazakhstan.

## **Article 103. Sanitary protection of the territory of the Republic of Kazakhstan**

1. Sanitary-quarantine control at checkpoints (sanitary-quarantine points) across the State Border of the Republic of Kazakhstan is conducted by territorial units of the state body for the sanitary-epidemiological welfare of the population.

2. It is not allowed to import dangerous cargo and goods, the import of which is prohibited, into the territory of the Republic of Kazakhstan, as well as cargo and goods, which, during the sanitary-quarantine supervision, were found as able to create a threat of the emergence and spread of infectious diseases or mass non-communicable diseases and poisoning in case of their import into the Republic of Kazakhstan.

3. Radiological control over cargo and goods, passengers at checkpoints across the State Border of the Republic of Kazakhstan is carried out by the state revenue authorities of the Republic of Kazakhstan.

## **Article 104. Conditions for introducing restrictive measures, including quarantine, in the event of a threat of epidemics, infectious diseases**

1. In the event of a threat of import of infectious and parasitic diseases into the Republic of Kazakhstan and (or) their spread throughout the entire territory of the Republic of Kazakhstan, the Chief State Sanitary Doctor of the Republic of Kazakhstan introduces restrictive measures, including quarantine, at checkpoints at the State Border of the Republic of Kazakhstan, which coincides with the customs border of the Eurasian Economic Union, or

throughout the territory of the Republic of Kazakhstan with special conditions for entrepreneurial and (or) other activities and life of the population.

2. In the event of a threat of the spread of infectious and parasitic diseases in corresponding administrative-territorial units (at individual facilities), the chief state sanitary doctors introduce restrictive measures, including quarantine, in corresponding administrative-territorial units (at individual facilities) with special conditions for entrepreneurial and (or) other activities and life of the population.

3. Restrictive measures, including quarantine, are introduced (canceled) by a resolution of the Chief State Sanitary Doctor of the Republic of Kazakhstan or the chief state sanitary doctor of a corresponding administrative-territorial unit (in the field of transport), as well as at departmental facilities of other state bodies by decision of the chief state sanitary doctor of structural units of the state body for the sanitary-epidemiological welfare of the population.

The decision of the chief state sanitary doctor is subject to publication (dissemination) in the media and to mandatory execution.

4. Operational management of activities of central and local executive bodies, individuals and legal entities in cases of imposition of restrictive measures, including quarantine, is assigned to the interdepartmental state commission for the prevention and elimination of emergency situations and territorial commissions for emergency situations.

5. The procedure for the implementation of restrictive measures, including quarantine, and the list of infectious diseases, the threat of the emergence and spread of which requires the introduction of restrictive measures, including quarantine, are established by the state body for the sanitary-epidemiological welfare of the population.

6. Restrictive measures, including quarantine, are introduced depending on territorial characteristics, contagiousness, transmission routes, mortality and other epidemically significant factors in the spread of infectious diseases in accordance with the criteria for determining the risks of importing infectious diseases from abroad into the territory of the Republic of Kazakhstan and (or) the occurrence of cases of infectious diseases identified by the authorized body.

6-1. In order to ensure compliance with restrictive measures, including quarantine, monitoring groups may be created by local executive bodies in the relevant administrative-territorial units.

Information about the established monitoring groups, composition and powers, as well as the algorithm of the monitoring group's actions shall be posted in the media and on the websites of local executive bodies.

The activities of such groups shall be carried out by monitoring the observance by individuals and legal entities of public order, sanitary and anti-epidemic, sanitary and preventive and restrictive measures, including quarantine, related to the prevention of the threat of the spread of infectious diseases.

Monitoring is an audit and shall not apply to other forms of state control and supervision.

To conduct monitoring, these groups shall carry out preliminary registration on the information resource in order to receive an act on the appointment of monitoring in electronic form, presented when visiting the facility.

Monitoring groups shall have the right to collect photo and video information indicating signs of violation of the decision of the Chief State Sanitary Doctor of the Republic of Kazakhstan and regulatory legal acts in the field of sanitary and epidemiological welfare of the population related to the prevention of the threat of the spread of infection, for its subsequent sending to a state body in the field of sanitary and epidemiological welfare of the population in the manner prescribed by the legislation of the Republic of Kazakhstan, without interfering in the work of business entities and without creating obstacles in the implementation of legitimate business activities.

The competence of monitoring groups shall not include the initiation of cases on administrative offenses.

If during the period of introduction of restrictive measures, including quarantine, as part of the monitoring group, a representative of a state body in the field of sanitary and epidemiological welfare of the population, in accordance with the procedure for creating monitoring groups and conducting monitoring, the monitoring group shall have the right to suppress violations of the conditions of restrictive measures, including quarantine, on the spot up to the suspension of the activities of business entities. In this case, the initiation of cases of administrative offenses shall be carried out directly by the representative of the state body in the field of sanitary and epidemiological welfare of the population.

Monitoring groups shall carry out their activities within the framework of regulatory legal acts in the field of sanitary and epidemiological welfare of the population and resolutions of the Chief Public Health Officer of the Republic of Kazakhstan related to the prevention of the threat of the spread of infection.

Based on the results of monitoring a business entity, in the event of violations of the requirements of the legislation of the Republic of Kazakhstan in the field of sanitary and epidemiological welfare of the population related to the prevention of the threat of the spread of infection, an official of the state body in the field of sanitary and epidemiological welfare of the population shall issue a resolution on conducting sanitary and anti-epidemic and sanitary and preventive measures. events.

The procedure for creating monitoring groups and conducting monitoring shall be determined by the state body in the field of sanitary and epidemiological welfare of the population.

When carrying out the activities of monitoring groups, business entities shall have the right to protect their rights and legitimate interests, including the inviolability of property, in accordance with the Entrepreneurial Code and the legislation of the Republic of Kazakhstan.

7. Restrictive measures, including quarantine, include:



- 1) restriction of entry into the territory of the Republic of Kazakhstan from abroad (exit from the territory of the Republic of Kazakhstan) and movement in certain regions (oblasts, cities of republican significance and the capital) using vehicles (by air, rail, road);
- 2) restriction of operation of facilities of entrepreneurial and (or) other activities;
- 3) restriction of the organization and holding of peaceful assemblies, entertainment, sports, religious and other mass events, as well as family rituals associated with birth, wedding, death;
- 4) restriction of production, import, export, use and sale of products intended for use and application by the population, as well as in entrepreneurial and (or) other activities, in the territory of the Republic of Kazakhstan;
- 5) carrying out non-contact thermometry measurement, laboratory examination and, if necessary, isolation of persons, arriving from countries with unfavorable infectious situation, at checkpoints at the State Border of the Republic of Kazakhstan;
- 6) referral of patients with infectious diseases for laboratory examination, isolation and hospitalization (or isolation at home), medical supervision, treatment;
- 7) referral of persons who are potential sources of the spread of infectious diseases, persons who have been in contact with infectious patients, as well as persons with suspected infectious disease, for laboratory and medical examination and isolation;
- 8) measures for personal and collective prevention of infectious diseases;
- 9) preventive and focal disinfection, disinsection and deratization measures in premises and vehicles, territories, foci of infectious diseases.

**Footnote. Article 104 as amended by the Law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced upon expiry of ten calendar days after the date of its first official publication).**

#### **Article 105. Registration and investigation of cases of infectious, parasitic diseases and (or) poisoning**

1. All cases of infectious and parasitic diseases and (or) poisoning, adverse events following immunization are subject to registration by public health entities at the place of their identification, state registration and reporting by state bodies and organizations of the sanitary-epidemiological service.
2. Cases of infectious and parasitic diseases and (or) poisoning of the population are subject to investigation by specialists of the state body for the sanitary-epidemiological welfare of the population.
3. The registration and investigation, recording and reporting of cases of infectious, parasitic diseases and (or) poisoning, adverse events following immunization are carried out in the manner prescribed by the authorized body.

4. Cases of HIV infection among the population are investigated by specialists of public health entities carrying out activities in the field of HIV prevention in the manner prescribed by the authorized body.

5. Within seven calendar days of receipt of an emergency notification, the state body for the sanitary-epidemiological welfare of the population, structural units of other state bodies carrying out activities in the field of sanitary-epidemiological welfare of the population conduct an epidemiological investigation of cases of infectious and parasitic diseases and (or) poisoning of the population.

6. In the case of registration of quarantine and especially dangerous diseases in troops, units and departmental organizations, the timing of epidemiological investigations approved by the authorized body may be changed by decision of the chief state sanitary doctors of other state bodies operating in the field of sanitary-epidemiological welfare of the population, depending on the place of registration.

#### **Article 106. Registration and investigation of cases of occupational diseases and (or) poisoning**

1. All cases of occupational diseases and (or) poisoning, including suspicions of occupational diseases and (or) poisoning caused by exposure of an employee to harmful production factors in connection with the employee's performance of his/her work (official) duties or other actions on his/her own initiative in the interests of the employer, are subject to registration by public health entities at the place of their identification in the manner prescribed by the authorized body.

2. Cases of occupational diseases and (or) poisoning are subject to registration with state healthcare organizations that provide specialized medical assistance in the field of occupational pathology and expertise, and to state registration and reporting by state bodies and organizations of the sanitary-epidemiological service.

3. Cases of occupational diseases and (or) poisoning caused by exposure of an employee to harmful production factors in connection with the employee's performance of his/her work (official) duties or other actions on his/her own initiative in the interests of the employer are subject to investigation.

4. Immediately, within 24 hours, the employer notifies the state body for the sanitary-epidemiological welfare of the population about all cases of occupational diseases and (or) poisoning associated with the employee's performance of his/her work (official) duties or other actions on his/her own initiative in the interests of the employer in accordance with the form established by the authorized state body for labor.

5. The employer is responsible for organizing the investigation of occupational diseases and (or) poisoning at work.

6. The employer ensures free access to officials of the state body for the sanitary-epidemiological welfare of the population for investigating cases of occupational diseases and (or) poisoning.

7. The organization of investigation of cases of occupational diseases and (or) poisoning, which occurred to seconded employees, is assigned to a legal entity to which the employee was seconded, with the participation of the employer's representative.

8. To resolve issues requiring an expert opinion, specialists from research organizations and (or) healthcare organizations providing specialized medical assistance in the field of occupational pathology and expertise are involved in the work of the commission for investigating occupational diseases and (or) poisoning, at the expense of the employer.

9. The investigation of circumstances and causes of the emergence of a chronic occupational disease and (or) poisoning in persons who, at the time of investigation, have no contact with a harmful production factor that caused this occupational disease, including nonworkers, is carried out at the place of previous work with a harmful production factor, taking into account the responsibility of all employers in proportion to the length of service in harmful conditions with each employer.

10. The conditions for investigating occupational diseases and (or) poisoning associated with work at high-security facilities are determined with account of features of access thereto.

#### **Article 107. Disinfection, disinsection and deratization**

1. In order to prevent the emergence, spread of infectious and parasitic diseases, individuals and legal entities are obliged, at their own expense, on a regular basis in accordance with the documents of the state sanitary-epidemiological regulation, to take preventive measures, and also disinfection, disinsection and deratization measures given epidemiological indications.

2. In the event of epidemic emergencies, by decision of the local executive body of a region, a city of republican significance and the capital, upon a recommendation of the state body for the sanitary-epidemiological welfare of the population, it is necessary to take extraordinary mandatory disinfection, disinsection or deratization measures using budgetary funds.

3. Preventive measures of disinsection and deratization (except for disinsection and deratization in natural foci of infectious diseases, as well as in foci of infectious diseases) are carried out by local executive bodies of regions, cities of republican significance, the capital, district, cities of regional significance.

4. Focal disinfection, disinsection, deratization measures in foci of infectious and parasitic diseases of humans and natural foci of infectious and parasitic diseases are carried out by organizations of the sanitary-epidemiological service and medical facilities in order to prevent and (or) eliminate infectious and parasitic diseases.

#### **Clause 2. Prevention of non-communicable diseases**

## **Article 108. Prevention of non-communicable diseases, including occupational diseases, and injuries**

1. The prevention of non-communicable diseases, including occupational ones, includes:
  - 1) the prevention of behavioral risk factors for diseases and raising public awareness by: promoting a healthy lifestyle and healthy diet;  
informing the population through the mass media together with introducing training programs on disease prevention;
  - 2) introduction of programs for the management of chronic non-communicable diseases;
  - 3) the monitoring of risk factors for diseases of the registered population by primary healthcare specialists, monitoring of occupational diseases with temporary disability of workers - by specialists of state bodies carrying out activities in the field of sanitary-epidemiological welfare of the population;
  - 4) minimization of the impact of work-related risk factors for diseases and control of health risks due to the impact of work-related harmful and (or) hazardous factors, taking into account their assessment by state bodies within their powers, other bodies and organizations, as well as individual entrepreneurs;
  - 5) identification of persons with chronic non-communicable diseases, including occupational ones, by conducting screening, preventive medical examinations of the population, and motivating early presentation;
  - 6) dynamic observation and timely rehabilitation of persons with chronic diseases, also occupational ones, including outpatient drug provision of certain categories of citizens of the Republic of Kazakhstan, medical rehabilitation;
  - 7) temporary transfer to lighter work for health reasons for the period specified in the medical report in the manner prescribed by the authorized body.

2. Injuries and occupational diseases shall be prevented at the intersectoral level by state bodies within their powers, by individuals and legal entities.

3. An organization's healthcare professional is obliged to:
  - 1) have knowledge of occupational health, occupational diseases associated with professional activities and working conditions of employees;
  - 2) analyze the incidence of temporary disability;
  - 3) provide a medical facility, carrying out mandatory medical examinations, with the description of the professional activity and working conditions of employees subject to mandatory preliminary and periodic medical examinations.

## **Article 109. Prevention of addiction to psychoactive substances**

1. The prevention of addiction to psychoactive substances includes:
  - 1) the promotion of knowledge of the harm caused by psychoactive substances, and also of medical-social and legal aspects of their use;

2) the prohibition to promote narcotic drugs, psychotropic substances and their analogues, including information on the techniques, methods of development, manufacture and use, places of their acquisition, production and distribution;

3) the prohibition of advertising of narcotic drugs, psychotropic substances and their analogues included in the list of narcotic drugs, psychotropic substances and precursors subject to control in the Republic of Kazakhstan, except for specialized printed publications designed for healthcare professionals and pharmaceutical workers, including distribution for advertising purposes of samples of medicinal products containing narcotic drugs or psychotropic substances;

4) voluntary anonymous treatment of persons addicted to psychoactive substances;

5) voluntary medical-social rehabilitation of drug addicts.

2. The prevention of addiction to psychoactive substances is carried out by all individuals and legal entities within their rights.

**Article 110. Prevention and control of consumption of tobacco products, including heated tobacco products, hookah tobacco, hookah mix, tobacco heating systems, electronic delivery systems and e-liquids, and alcohol**

1. The prevention and control of consumption of tobacco products, including heated tobacco products, hookah tobacco, hookah mix, heating tobacco systems, electronic delivery systems and e-liquids, as well as alcohol, are aimed at protecting public health from the consequences of their consumption and preventing the emergence of addiction, including that caused by new types of systems of nicotine delivery and tobacco consumption, heating tobacco systems, electronic delivery systems, hookah, introducing an age requirement for persons entitled to purchase tobacco products, forming public attitudes towards the consumption of tobacco products and alcohol as high risk factors for life and health, taking concerted action to prevent the spread of alcohol and tobacco consumption in accordance with international obligations.

2. It is prohibited to sell tobacco products, including heated tobacco products, hookah tobacco, hookah mix, tobacco heating systems, electronic delivery systems and e-liquids:

1) to persons under the age of twenty-one;

2) by persons under the age of eighteen;

3) from open packs of tobacco products or to sell tobacco products by the piece;

4) without direct participation of a seller using vending machines, other electronic or mechanical devices;

5) in buildings and premises of healthcare organizations, educational institutions, health and fitness, sports and sports-technical facilities, stadiums;

6) without relevant documents confirming the products' quality;

7) without means of identification applied to the pack of tobacco products;

8) if there are less than twenty cigarettes in a pack of tobacco products;

9) without information on a pack of tobacco products, package of a tobacco product on at least three harmful compounds - systemic poisons, carcinogenic and mutagenic substances, which shall be placed on a pack of tobacco products, package of a tobacco product;

10) without warnings about harm caused by the consumption of tobacco products and nicotine on a pack of tobacco products, including heated tobacco products, hookah tobacco, hookah mix, heating tobacco systems;

11) without an inscription prohibiting the sale to persons under the age of twenty-one and persons under the age of eighteen on a pack of tobacco products, consumer package, including heated tobacco products, hookah tobacco, hookah mix, heating tobacco systems, electronic delivery systems and e-liquids;

12) which contain information directly or indirectly misleading the consumer, including such words as “low-tar”, “light”, “ultra-light”, “mild”, “extra”, “ultra” or others phrases, also in foreign languages, any terms, descriptions, signs, symbols or other designations that create a false impression about lesser harm of certain products and (or) methods of consumption in comparison with other products and (or) methods of consumption, and also evoking associations with foods (food additives), including fruits, berries, confectionery;

13) as part of sets with other goods;

14) from self-service shelves;

15) in the premises of trade organizations selling children’s goods;

16) with the display and open demonstration of tobacco products, including heated tobacco products, hookah tobacco, hookah mix, heating tobacco systems, electronic delivery systems and e-liquids. In case of retail trade, information on tobacco products, including heated tobacco products, hookah tobacco, hookah mix, tobacco heating systems, electronic delivery systems and e-liquids is brought to the attention of buyers by posting a list of products sold, the text of which is typed in same-size black letters on a white background, the size of not more than 40x30 centimeters per a sales place and compiled in alphabetical order, indicating the price of saleable tobacco products, without any graphic images and drawings. Tobacco products, including heated tobacco products, hookah tobacco, hookah mix, heating tobacco systems, electronic delivery systems and e-liquids can be presented to the buyer in a shopping facility at his/her request after reviewing the list of saleable tobacco products, electronic delivery systems and e-liquids;

17) in the premises of and inside (except for duty-free trade) railway stations, bus stations, airports, seaports, river ports, at underground stations intended for providing passenger transportation services, in the premises intended for providing housing and hotel services, services for temporary accommodation and (or) temporary residence, consumer services.

3. In places where tobacco products are sold, including heated tobacco products, hookah tobacco, hookah mix, tobacco heating systems, electronic delivery systems and e-liquids, the following inscription shall be placed in a conspicuous place: “The sale of tobacco products, including heated tobacco products, hookah tobacco, hookah mix, tobacco heating systems,

electronic delivery systems and e-liquids is prohibited to persons under the age of twenty-one”, as well as a warning about the harm caused by smoking, which shall be approved by the authorized body.

4. Persons selling tobacco products, including products with heated tobacco, hookah tobacco, hookah mixture, tobacco heating systems, electronic consumption systems and liquids for them, in case of doubt that the buyer is twenty-one years old, shall be obliged:

1) require to present an identity document;

2) refuse to sell tobacco products, including products with heated tobacco, hookah tobacco, hookah mixture, tobacco heating systems, electronic consumption systems and liquids for them, in the event that an identity document has not been presented.

5. The consumption of tobacco products, including heated tobacco products, hookah tobacco, hookah mix, tobacco heating systems, electronic delivery systems and e-liquids, is prohibited:

1) inside and in the premises of educational institutions, and also in organizations for the recreation of minors;

2) in the premises of healthcare organizations;

3) in public catering facilities;

4) in cultural facilities, museums, libraries and lecture halls, cinemas, theaters, circuses, concert, viewing and exhibition halls, sports organizations and health-fitness organizations, in sports arenas and other facilities intended for public recreation;

5) in night clubs, discos;

6) on local and long-distance trains, on aircraft, sea and river vessels, as well as inside urban, suburban and intercity road public transport, in the underground, in public transport performing regular and irregular road transportation of passengers and luggage, taxis;

7) in the buildings of airports, railway, automobile and water stations, at public bus shelters;

8) in the buildings of state bodies and organizations;

9) in the premises that are workplaces and work areas;

10) in the entrances of houses;

11) inside and in the premises of gas stations;

12) in playgrounds;

13) in underpasses;

14) inside a motor vehicle with minors.

6. The provisions of subparagraphs 3) and 7) of paragraph 5 of this article shall not apply given specially equipped places for the consumption of tobacco products, including heated tobacco products, heating tobacco systems, electronic delivery systems and e-liquids.

7. Places allocated specifically for the consumption of tobacco products, including heated tobacco products, heating tobacco systems, electronic delivery systems and e-liquids, shall be

equipped in accordance with the requirements established by the state body for the sanitary-epidemiological welfare of the population.

8. It is prohibited to import, manufacture, sell and distribute smoking tobacco products, including heated tobacco products, hookah tobacco, hookah mix, tobacco heating systems, electronic delivery systems and e-liquids, with exceeded maximum permissible levels of nicotine and tar substances determined by the state body for the sanitary-epidemiological welfare of the population, and also tobacco products for which sanitary-epidemiological requirements have not been established.

9. The import, manufacture, sale and distribution of smokeless tobacco products are prohibited.

10. The manufacture, sale and distribution of imitation tobacco products are prohibited.

11. There shall be signs prohibiting the consumption of tobacco products, including heated tobacco products, heating tobacco systems, electronic delivery systems and e-liquids, indicating the amount of a fine, in places, and also at the entrance, where their consumption is prohibited.

12. A pack of a smoking tobacco product, package of a smoking tobacco product shall have a warning about harm caused by the consumption of tobacco products in accordance with the requirements approved by the Technical Regulations for tobacco products of the Eurasian Economic Union.

The consumer package of tobacco products, including heated tobacco products, hookah tobacco, hookah mix, shall have a warning about harm caused by the consumption of tobacco and nicotine, which shall meet the following requirements:

1) it shall occupy at least sixty-five percent of each larger side of a pack of tobacco products, package of tobacco products, including heated tobacco products, hookah tobacco, hookah mix;

2) it may not be printed on clear wrap or any other outer wrapping material;

3) it shall be executed in the form of color drawings (pictograms, graphics) or photographic images, including text.

The text of the warning about the dangers of using tobacco products must comply with the requirements of the Law of the Republic of Kazakhstan “On languages in the Republic of Kazakhstan”.

Sketches of warnings about harm caused by the consumption of tobacco products and nicotine are approved by the authorized body.

A manufacturer, an importer shall put the sketches of warnings on a consumer package of tobacco products in accordance with the sketches within twelve months of their approval.

The sketches of warnings are put on the equal number of consumer packages of tobacco products, including heated tobacco products, hookah tobacco, hookah mix.

13. Annually, by February 1 of a year following a reporting period, a manufacturer, importer of tobacco products, including heated tobacco products, electronic delivery systems



and e-liquids, shall submit reports on the results of laboratory tests on the maximum permissible nicotine content in all brands of tobacco and tobacco products, including heated tobacco products, electronic delivery systems and e-liquids, in the manner approved by the authorized body.

14. Research on the level of nicotine and other harmful compounds, carcinogenic and mutagenic substances in tobacco products, including heated tobacco products, hookah tobacco, hookah mix, electronic delivery systems and e-liquids, is carried out by the manufacturer, importer of tobacco products, including heated tobacco products, hookah tobacco, hookah mix, electronic delivery systems and e-liquids, at their own expense in laboratories accredited as required by the legislation of the Republic of Kazakhstan.

15. It is prohibited to sell by retail:

1) alcoholic beverages to persons under the age of twenty-one;

2) alcoholic beverages, except for sales in restaurants, bars and cafes:

between 23.00 and 08.00;

with a volume fraction of ethyl alcohol over thirty percent - between 21:00 and 12:00;

3) in other cases provided for by the laws of the Republic of Kazakhstan.

16. It shall be prohibited to sponsor and advertise tobacco, tobacco products, advertising of alcoholic products, products imitating alcoholic beverages.

Individuals and legal entities engaged in the import, manufacture, sale and distribution of tobacco are allowed to provide charitable assistance in the manner prescribed by the legislation of the Republic of Kazakhstan.

17. Minors are prohibited from using alcoholic beverages, tobacco and tobacco products, including heated tobacco products, hookah tobacco, hookah mix, tobacco heating systems, as well as electronic delivery systems and e-liquids.

Parents and other legal representatives of minors bear administrative responsibility for the consumption of alcoholic beverages by minors in accordance with the laws of the Republic of Kazakhstan.

18. When selling alcoholic products, persons engaged in the sale of alcoholic products, in case of doubt that the buyer has reached the age of twenty-one, shall be obliged:

1) require to present an identity document;

2) refuse to sell alcoholic products if an identity document has not been presented.

**Footnote. Article 110 as amended by the Law of the Republic of Kazakhstan dated 02.01.2021 № 399-VI (shall be enforced upon expiration of ten calendar days after the date of its first official publication ): dated 29.12.2021 № 94-VII (shall be enforced upon expiry of ten calendar days after the date of its first official publication); dated 31.12.2021 № 100 (shall be enforced from 01.01.2022).**

**Article 111. Prevention of iron deficiency anemia**

1. Iron deficiency anemia is a pathological process of the body caused by insufficient intake of iron in the body with food, absorption of iron in the body and an increase in iron loss in some chronic diseases of the gastrointestinal tract, genitourinary system and blood system, increased need for iron.

2. Measures for the iron deficiency prevention are carried out based on the principles of:

1) responsibility of state bodies, individuals and legal entities for ensuring and complying with the requirements for the production, import, export, sale of fortified foods and their movement at other stages of the distribution in the Republic of Kazakhstan;

2) prophylactic provision of target population groups with ferriferous medicines;

3) enrichment (fortification) of flour and other foods with ferriferous vitamins, minerals and other substances.

3. High-grade and first-grade wheat flour sold (distributed) in the Republic of Kazakhstan is subject to enrichment (fortification) with ferriferous vitamins, minerals and other substances.

The procedure for enrichment (fortification) and market distribution of foods subject to mandatory fortification is determined by the state body for the sanitary-epidemiological welfare of the population.

#### **Article 112. Prevention of iodine deficiency disorders**

1. Iodine deficiency disorders are a pathological condition of the body caused by dysfunction of the thyroid gland associated with insufficient intake of iodine in the body.

2. The prevention of iodine deficiency disorders is a system of measures to prevent iodine deficiency disorders aimed at:

1) the protection of public health;

2) carrying out coordinated measures for the prevention of iodine deficiency disorders in the Republic of Kazakhstan;

3) the development of production and sale of foods enriched with iodine compounds.

3. Measures for the prevention of iodine deficiency disorders are carried out based on the principles of responsibility of state bodies, individuals and legal entities for ensuring and complying with the requirements for the production, import, export, sale of iodized edible and fodder salt in the Republic of Kazakhstan.

4. The requirements for the production, distribution and safety of salt are as follows:

1) edible and fodder salt imported, produced and (or) sold in the Republic of Kazakhstan shall be iodized, except for salt intended for:

persons with contraindications to the use of iodized salt;

production of certain types of foods produced using non-iodized salt.

The procedure for the import, production and sale of non-iodized edible salt is determined by the state body for the sanitary-epidemiological welfare of the population;

2) the iodine level in salt, its quality, safety, iodization methods, the process of re-iodization in case of a decrease in the iodine level shall comply with regulatory legal acts in the field of sanitary-epidemiological welfare of the population;

3) the production, import, and also sale of non-iodized salt in the Republic of Kazakhstan is prohibited, except for the cases specified in items two and three of subparagraph 1) of paragraph 4 of this article;

4) the production, import, export and (or) sale of fake salt is prohibited.

5. The requirements for iodized edible salt are as follows:

1) iodized edible salt intended for sale in the Republic of Kazakhstan is subject to mandatory confirmation of conformity in accordance with the legislation of the Republic of Kazakhstan in the field of technical regulation;

2) it is not allowed to import and sell iodized edible salt without a certificate of conformity issued in accordance with the legislation of the Republic of Kazakhstan in the field of technical regulation.

6. The production of foods enriched with iodine compounds, as well as conditions for their storage, transportation and sale shall comply with the requirements established by the legislation of the Republic of Kazakhstan.

7. Individuals and legal entities engaged in the production and sale of foods enriched with iodine compounds shall guarantee their good quality and safety to consumers, compliance with regulatory legal acts in the field of sanitary-epidemiological welfare of the population.

### **Article 113. Public health and the environment**

1. When developing strategic documents on state planning, it is necessary to assess risks to human health within strategic environmental examination.

2. In order to improve the state of the environment, the authorized body creates a system for monitoring the state of the environment, including indoors, and for preparing an updated assessment of risks of pollutants' impact on public health.

3. State bodies and organizations of the sanitary and epidemiological service conduct sanitary and epidemiological monitoring in accordance with the procedure determined by the state body in the field of sanitary and epidemiological welfare of the population, taking into account the methodology of biological risk management and requirements for the assessment of biological risks.

The results of sanitary-epidemiological monitoring (the state of environmental objects) are entered into the Unified State System for Monitoring the Environment and Natural Resources.

4. Local representative bodies approve target indicators of environmental quality.

Target indicators of environmental quality are determined with account of environmental problems of a region and provide for indicators of the state of atmospheric air with the development of a set of measures to reduce pollution.

5. In order to raise public awareness, the authorized body develops and sends recommendations on the population's actions, depending on the level of air pollution and other environmental factors, to local executive bodies.

Local executive bodies ensure the provision of the population with information on the state of atmospheric air.

6. Issues of public health and the environment are considered within the framework of cooperation of state bodies and public associations.

7. Local executive bodies ensure the creation of favorable conditions for public recreation.

In order to reduce the negative impact of noise on public health, the activities accompanied by increased noise, not related to an urgent need, preventing the normal rest and peace of mind of individuals, in and out of residential buildings, shall be carried out during the daytime and not exceed 8 hours a day.

8. Activities accompanied by increased noise may not be carried out in the premises of residential buildings and in areas of residential development between 22:00 and 09:00, in entertainment establishments - between 22:00 and 09:00 on weekdays, between 23:00 and 10:00 - on weekends and holidays.

The state body for the sanitary-epidemiological welfare of the population arranges for the sanitary-epidemiological monitoring of noise.

Local executive bodies ensure the development of noise maps in residential areas and their implementation in accordance with the results of sanitary-epidemiological monitoring.

9. In order to assess the epidemiological situation in an area and determine potential danger of the impact of water used for household and drinking needs by the population on public health, the state body for the sanitary-epidemiological welfare of the population arranges for the sanitary-epidemiological monitoring of water.

The use of water for household and drinking needs by the population from water supply sources located in an area that is in private ownership is allowed if the water safety indicators comply with the established hygienic standards.

**Footnote. Article 113 as amended by the Law of the Republic of Kazakhstan dated 21.05.2022 № 123-VII (shall be enforced six months after the date of its first official publication).**

#### **Article 114. Sanitary-epidemiological monitoring**

1. Sanitary-epidemiological monitoring is a state system for monitoring the state of public health and the environment, their analysis, assessment and forecast, and also the determination of causal relationships between the state of public health and the impact of the environment.

2. The goals of sanitary-epidemiological monitoring are to obtain reliable information on the impact of the environment (chemical, physical, biological factors) on human health, to

assess the effectiveness of measures taken to prevent the occurrence of poisoning and outbreaks of infectious, parasitic and occupational diseases, to predict their emergence.

3. Sanitary-epidemiological monitoring and assessment of effectiveness of the activities performed are carried out to identify their compliance with the requirements of the documents of the state system of sanitary-epidemiological regulation.

4. Sanitary-epidemiological monitoring is carried out in relation to facilities and products subject to sanitary-epidemiological control and supervision, environmental objects (soil, water, air) following the results of laboratory and instrumental studies (measurements), indicators of infectious, parasitic, non-infectious and occupational morbidity.

5. Sanitary-epidemiological monitoring is carried out by state bodies and organizations of the sanitary-epidemiological service in the manner and as frequently as determined by the state body for the sanitary-epidemiological welfare of the population.

6. Sanitary-epidemiological monitoring can be carried out with a visit to (for taking samples from environmental objects, measuring physical factors) and without visiting an object. The results of sanitary-epidemiological monitoring are not a ground for scheduling inspections, preventive control.

7. Sanitary-epidemiological monitoring is carried out in stages and includes:

1) the collection, processing, systematization of (digital, analytical) data on the state of public health and the human environment following the results of sanitary-epidemiological examinations of facilities subject to state sanitary-epidemiological control and supervision, using laboratory and instrumental research methods;

2) analysis and identification of causal relationships between the state of health and the human environment, the reasons and conditions for changes in the sanitary-epidemiological welfare of the population following the results of laboratory and instrumental studies of products and objects of sanitary-epidemiological control and supervision;

3) identification of environmental factors and selection of key indicators of health disorders to optimize laboratory control in the system of sanitary-epidemiological monitoring;

4) in case of detection of infectious and mass non-communicable diseases (poisoning), the establishment of the causes and conditions of their emergence and spread;

5) interdepartmental cooperation in sanitary-epidemiological monitoring in order to ensure the sanitary-epidemiological welfare of the population;

6) the assessment and forecast of changes in the state of public health due to changes in the human environment;

7) the determination of urgent and long-term measures to prevent and eliminate the impact of harmful factors on public health;

8) the creation of information and analytical systems, networks, software materials and databases of sanitary-epidemiological monitoring of a district, city, region and the republic and the storage of sanitary-epidemiological monitoring data.

8. The data of sanitary-epidemiological monitoring are used in the work of the bodies of the sanitary-epidemiological service, local executive and other state bodies.

9. Pursuant to the results of sanitary-epidemiological monitoring:

1) summaries, reports, recommendations, scientific forecasts, diagrams, tables are compiled, which describe the dynamics, direction and intensity of the development of changes;

2) managerial decisions are made in order to eliminate violations of regulatory legal acts in the field of sanitary-epidemiological welfare of the population in the Republic of Kazakhstan.

10. The results of sanitary-epidemiological monitoring are posted on the official website the state body for the sanitary-epidemiological welfare of the population and its territorial bodies at half-year end, at year end.

11. In cases of exceeded morbidity rates, deteriorated indicators of the state of controlled objects and environmental objects, the results of sanitary-epidemiological monitoring are submitted for the consideration of concerned state bodies to make managerial decisions.

### **SECTION 3. PROVISION OF MEDICAL ASSISTANCE**

#### **Chapter 16. GENERAL RULES FOR THE PROVISION OF MEDICAL ASSISTANCE**

##### **Article 115. Organization of medical assistance**

1. Medical assistance is organized by the authorized body, central executive bodies and other central state bodies having military-medical (medical) units, local public health authorities of regions, cities of republican significance and the capital; healthcare entities provide medical assistance in the manner prescribed by this Code.

2. Healthcare entities providing medical assistance are obliged to:

1) provide timely and high-quality medical assistance;

2) use methods of prevention, diagnosis, treatment and medical rehabilitation with the greatest proven effectiveness and safety;

3) be prepared to work in an emergency situation, military conflict and in case of an act of terrorism;

4) take measures for the prophylaxis, prevention, diagnosis, treatment and medical rehabilitation of diseases that pose a danger to others, as well as occupational diseases;

5) provide individuals with free, prompt and reliable information on the forms and types of medical assistance;

6) comply with regulatory legal acts in the field of sanitary-epidemiological welfare of the population and hygienic standards;

7) interact with other healthcare entities and ensure consistency in their activities;

8) form a healthy lifestyle and healthy diet;

9) maintain medical source statements and submit reports in the forms and in the manner established by the authorized body, with account of the requirements of the Law of the Republic of Kazakhstan “On State Secrets” and the specific nature of their activities;

10) submit information (expedited report):

on cases of infectious diseases, poisoning, which pose a danger to others, - to the state body for the sanitary-epidemiological welfare of the population;

on cases of death of pregnant women, women in labor, parturient women within forty-two calendar days after childbirth, sudden death of patients during the provision of routine medical assistance (primary medical and specialized medical, including high-tech, assistance) - to the state body for providing medical services (assistance);

on the threat of emergence and (or) the emergence of medical-sanitary consequences of emergency situations - to the authorized body for civil protection;

on persons who complained about recent injuries, wounds, illegal abortion, domestic violence, cases of diseases that pose a danger to others - to the internal affairs bodies.

3. Healthcare entities provide medical assistance in accordance with the standards for the provision of medical assistance, the rules for the provision of medical assistance, as well as clinical protocols.

#### **Article 116. Levels of providing medical assistance**

The Republic of Kazakhstan has a three-tier system of providing medical assistance, which includes:

1) primary level - the level of medical assistance provided by primary healthcare specialists in outpatient, hospital-replacing conditions and at home;

2) secondary level - the level of medical assistance provided by specialized professionals who provide specialized medical assistance in outpatient, hospital-replacing and inpatient conditions, also pursuant to the referral from specialists providing medical assistance at the primary level;

3) tertiary level - the level of medical assistance provided by specialized professionals providing specialized medical assistance with the use of high-tech medical services in outpatient, hospital-replacing and inpatient conditions, also pursuant to the referral from specialists of the primary and secondary levels.

#### **Article 117. Forms of medical assistance**

Medical assistance is provided in:

1) the urgent form - medical assistance provided in case of sudden acute diseases and conditions, exacerbation of chronic diseases requiring urgent medical intervention to prevent significant harm to health and (or) eliminate the threat to life;

2) the emergency form - medical assistance provided in case of sudden acute diseases and conditions, exacerbation of chronic diseases that do not pose an obvious threat to the patient's life;

3) the planned form - medical assistance provided in case of diseases and conditions not endangering the patient's life, a delay in the provision of which for a certain time will not deteriorate the patient's condition, as well as that provided during preventive measures.

#### **Article 118. Conditions for the provision of medical assistance**

1. Medical assistance is provided:

1) on an outpatient basis without round-the-clock medical supervision and treatment, including in the admission departments of round-the-clock hospitals;

2) in inpatient conditions with round-the-clock medical supervision, treatment, care, and also with the provision of a bed and meals, as well as in the event of day-case therapy and surgery with round-the-clock supervision during the first day after the start of treatment;

3) in hospital-replacing conditions that do not require round-the-clock medical supervision and treatment and provide for medical supervision and treatment during the day with the provision of a bed;

4) at home: when calling a healthcare professional, a mobile team, in case of active nursing by healthcare professionals, when organizing treatment at home (hospital at home);

5) in sanatoriums and health resorts;

6) outside a medical facility: at the place where the ambulance team is called, on ambulance vehicles and medical aviation during transportation, as well as on medical trains, mobile (field) medical complexes, field hospitals, en-route medical rescue points and when providing telemedicine services.

2. The route of providing medical assistance to patients at the primary, secondary and tertiary levels in the context of profiles is established by local public health authorities of regions, cities of republican significance and the capital in accordance with the rules and standards for the provision of medical assistance.

3. Healthcare organizations provide medical assistance based on the triage principle (medical or sanitary triage of patients) depending on the severity of their condition and sanitary-epidemiological risk.

Medical facilities observe the principles of infection control aimed at preventing the emergence and spread of infectious diseases there.

#### **Article 119. Features of provision of medical assistance at the rural healthcare level**

1. Services for health promotion, prevention, treatment and rehabilitation shall be available to the rural population at all levels of rural healthcare.



2. To provide access to primary medical assistance and specialized medical assistance at the level of rural healthcare, it is necessary to use mobile medical complexes, medical trains and means of providing telemedicine services.

3. When planning the volume of medical assistance for rural healthcare, it is necessary to take into account the geographical remoteness, population density, demographic indicators, gender and age composition and other criteria affecting the access to medical assistance.

4. Local public health authorities are responsible for ensuring access to medical assistance for the rural population at all levels of providing medical assistance.

#### **Article 120. Types of medical assistance**

The types of medical assistance are as follows:

- 1) emergency medical care;
- 2) paramedic assistance;
- 3) primary medical care;
- 4) specialized medical assistance, including high-tech one;
- 5) medical rehabilitation;
- 6) palliative care.

#### **Article 121. Emergency medical care**

1. Emergency medical care is a system for organizing medical assistance in an emergency and urgent form for acute diseases and conditions that threaten life, and also for preventing significant harm to health at the scene of an accident and (or) on-route to a medical facility.

2. Emergency medical care with the involvement of medical aviation is provided:

1) if it is impossible to provide medical assistance because a medical facility at the location of the patient lacks medical products and (or) specialists of required qualifications;

2) if it is necessary to deliver specialists of the secondary and tertiary levels of medical assistance to the destination;

3) for the transportation of a patient to medical facilities of the secondary and tertiary levels of medical assistance in case of impossibility and ineffectiveness of medical care at the location of the patient;

4) for the transportation of organs (parts of an organ) and (or) tissues (parts of tissue) for subsequent transplantation to a relevant medical facility.

3. Medical aviation can be used to:

1) deliver a very ill patient from foreign clinics to domestic ones;

2) deliver a patient in need of medical escort from medical facilities of the secondary and tertiary levels of medical assistance to medical facilities at the place of residence to continue treatment.

4. Rules for the provision of emergency medical care, also with the involvement of medical aviation, are developed and approved by the authorized body.

5. Local public health authorities of regions, cities of republican significance and the capital are responsible for ensuring the access to and timely provision of emergency medical care.

#### **Article 122. Paramedic assistance**

1. Pre-medical care - medical care provided by paramedical workers independently or as part of a multidisciplinary team, including health promotion, assessment of the patient's condition, making a pre-medical diagnosis, prescribing a plan for pre-medical interventions, performing pre-medical manipulations and procedures and caring for patients, persons with disabilities and dying people.

2. Paramedics provide medical assistance in accordance with the rules for the provision of paramedic assistance approved by the authorized body.

3. Local public health authorities of regions, cities of republican significance and the capital are responsible for ensuring the accessibility of paramedic assistance.

**Footnote. Article 122 as amended by the Law of the Republic of Kazakhstan dated 27.06.2022 № 129-VII (shall be enforced ten calendar days after the date of its first official publication).**

#### **Article 123. Primary medical care**

1. Primary medical care is a place of the first access to medical care focused on the needs of the population, including prevention, diagnosis, treatment of diseases and conditions provided at the level of an individual, family and society, including:

- 1) diagnosis, treatment and management of the most common diseases;
- 2) preventive examinations of target population groups (children, adults);
- 3) early identification and monitoring of behavioral risk factors for diseases and training in the skills to reduce the identified risk factors;
- 4) immunization;
- 5) formation and promotion of a healthy lifestyle;
- 6) measures to protect reproductive health;
- 7) observation of pregnant women and new mothers in the postpartum period;
- 8) sanitary-antiepidemic and sanitary-preventive measures in the foci of infectious diseases.

2. Healthcare organizations providing primary medical care carry out their activities based on such principles as:

- 1) the family service principle;
- 2) territorial access to primary medical care;

3) free choice of a medical facility that can be accessed within their district in accordance with subparagraph 2) of paragraph 2 of this article;

4) the patient's satisfaction with the quality of medical care;

5) equality and fair competition regardless of the form of ownership and departmental affiliation;

6) primary medical services covering prevention, diagnosis and treatment, which are available to all patients regardless of their location.

3. Primary medical care is provided by general practitioners (family doctors), district therapists, pediatricians, paramedics, obstetricians, advanced practice (general practice) nurses, district nurses, social workers, healthcare psychologists.

4. To receive primary medical care, individuals shall register with healthcare entities providing primary medical care.

The registration of an individual with a primary medical care facility is the basis for exercising the right to receive medical care and fulfilling the obligations of healthcare organizations to provide medical care within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance.

The rules for individuals' registration with healthcare organizations providing primary medical care are developed and approved by the authorized body.

5. Primary medical care facilities set up emergency departments (points) for the provision of emergency care.

6. Local public health authorities of regions, cities of republican significance and the capital are responsible for ensuring the accessibility of primary medical care.

#### **Article 124. Specialized medical assistance, including high-tech one**

1. Specialized medical assistance is provided by specialized professionals for diseases requiring special methods of diagnosis, treatment, medical rehabilitation, including the use of telemedicine services.

2. Specialized medical assistance is provided in the form of consultative and diagnostic assistance on an outpatient basis, stationary and inpatient care at the secondary and tertiary levels of medical assistance.

3. High-tech medical assistance is part of specialized medical assistance provided by specialized professionals for diseases requiring the use of innovative and (or) unique methods of diagnosis and treatment with scientifically proven effectiveness and safety and technologies developed on the basis of the achievements of medical science and related branches of science and technology.

4. The procedure for determining types of high-tech medical assistance and their list, as well as the criteria for transferring types of high-tech medical assistance into the list of specialized medical services, are determined by the authorized body.

5. The rules for the provision of specialized medical assistance, including high-tech one, are developed and approved by the authorized body.

#### **Article 125. Medical rehabilitation**

1. Medical rehabilitation is provided to persons with congenital diseases, after acute conditions, surgical interventions, injuries, as well as their consequences, according to the list approved by the authorized body.

2. Medical rehabilitation for persons with congenital diseases, after acute conditions, surgical interventions and injuries is provided when treating the underlying disease in outpatient, inpatient, hospital-replacing conditions of medical facilities of primary, secondary and tertiary levels.

2-1. Medical rehabilitation to persons held in pre-trial detention centers and institutions of the penal (penitentiary) system, shall be provided after acute conditions, surgical interventions, injuries, as well as their consequences according to the list determined by the authorized body.

3. Medical rehabilitation of congenital diseases, the consequences of acute conditions, surgical interventions and injuries is provided with account of the rehabilitation potential in accordance with the medical part of the individual rehabilitation program of the patient in outpatient, inpatient, hospital-replacing conditions of medical facilities of primary, secondary and tertiary levels, as well as at home and in sanatorium-resort facilities in the manner prescribed by the authorized body.

4. A patient with a lack of rehabilitation potential is not provided with medical rehabilitation pursuant to the opinion of the multidisciplinary team.

5. Medical habilitation is a process of medical rehabilitation aimed at acquiring or compensating for the unformed functions and skills of children with disabilities and integrating them into society. Medical habilitation is carried out for children with congenital functional limitations until they reach the age of three years.

6. The procedure for the provision of medical rehabilitation is developed and approved by the authorized body.

**Footnote. Article 125 as amended by the Law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.07.2022); dated 27.06.2022 № 129-VII ( shall be enforced ten calendar days after the date of its first official publication).**

#### **Article 126. Palliative medical care**

1. Palliative care is a range of services aimed at improving the quality of life of patients with severe and incurable diseases (conditions), as well as their families and caregivers, including medical, special social services, spiritual support.

2. Palliative care is a range of medical services aimed at relieving pain and severe manifestations of a disease (condition) of a terminally ill patient in the absence of indications for radical treatment.

Palliative care is provided on the basis of a healthcare standard developed and approved by the authorized body.

### **Article 127. Nursing activities**

1. Nursing activities include nursing care delivered by nurses and advanced practice nurses independently or as part of multidisciplinary teams.

A nurse is a specialist with technical and professional medical education in the field of nursing who provides nursing care independently or under the supervision of an advanced practice nurse or a physician.

An advanced practice nurse is a specialist with post-secondary or tertiary nursing education who performs advanced nursing functions in care.

2. Nursing care is provided in cases that do not require round-the-clock medical supervision, in specialized structural units (departments, wards, beds, offices) of healthcare organizations, independent specialized medical facilities (nursing hospitals) in inpatient, hospital-replacing conditions and at home, also using mobile teams.

3. Nurses and advanced practice nurses provide nursing care in accordance with the legislation of the Republic of Kazakhstan, the rules for the provision of nursing care, and also follow clinical nursing guidelines.

4. Clinical nursing guidelines are scientifically proven guidelines for best practice in a specific clinical area, which are developed and systematically updated by professional medical associations.

5. Advanced practice nurses have the right to provide independent professional nursing care, including nursing assessment of the patient's (client's) condition, making a nursing diagnosis, prescribing a nursing intervention plan and effectiveness monitoring, in accordance with clinical protocols and clinical nursing guidelines.

6. Rules for the provision of nursing care are developed and approved by the authorized body. The rights and obligations of nurses and advanced practice nurses providing nursing care are established in accordance with these rules.

7. Local public health authorities in regions, cities of republican significance and the capital are responsible for ensuring the accessibility of nursing care.

### **Article 128. Integrated model of providing medical assistance**

1. An integrated model of medical assistance is a model of organizing the provision of a complex of medical and social services throughout a person's life for the prevention, timely

identification, treatment and reduction of the risk of developing complications of the disease in order to increase life expectancy.

2. An integrated model of providing medical assistance is implemented through a multidisciplinary approach in accordance with clinical protocols, standards and rules for the provision of medical assistance.

#### **Article 129. Features of the provision of telemedicine services**

1. Telemedicine services are provided for:

- 1) giving advice, including by specialists from research institutes, research centers, university hospitals, as well as foreign clinics;
- 2) expedient referral of a patient for an in-person consultation at higher levels of medical assistance;
- 3) receiving practical assistance from specialists of the secondary and tertiary levels by specialists of the primary level and rural healthcare;
- 4) evaluating the effectiveness of treatment and diagnostic measures, medical observation of the patient's health status;
- 5) the clarification of the diagnosis, adjustment and determination of further tactics of patient management and prescription of therapy-diagnostic measures;
- 6) determining the possibility of transporting a patient to higher levels of medical assistance, including the feasibility of using medical aviation equipment;
- 7) organizing electronic consultations;
- 8) the provision of medical rehabilitation services.

2. An opinion of doctors providing telemedicine services on the health status and diagnosis of the patient is an official document and shall be entered in the patient's electronic health passport using the electronic digital signature of the doctor, and in the cases provided for in subparagraph 8) of paragraph 1 of this article, using the electronic digital signature of a specialist who provided medical rehabilitation services.

3. Certified wearable medical devices are used to assess the physiological parameters and health status of a patient.

4. Telemedicine services are provided in compliance with the requirements established by the legislation of the Republic of Kazakhstan in the field of personal data protection and for medical confidentiality.

5. The organization, procedure for the provision and payment of telemedicine services are determined by the authorized body.

#### **Article 130. Laboratory diagnostics**

1. Laboratory diagnostics is a complex of laboratory studies of biomaterials of patients aimed at diagnosing a disease, monitoring the effectiveness of treatment and correcting treatment.

2. The standard for the organization of laboratory diagnostics is developed and approved by the authorized body.

3. External assessment of the quality of measurements of laboratory tests is controlled and carried out by reference laboratories in the manner prescribed by the authorized body.

4. The list of reference laboratories, regulations on their activities, as well as criteria and requirements for their selection, are approved by the authorized body.

5. Local public health authorities of regions, cities of republican significance and the capital are responsible for ensuring the accessibility of laboratory diagnostics.

### **Article 131. Pathoanatomical diagnosis**

1. Pathoanatomical diagnosis is carried out in order to identify a diagnosis by analyzing the totality of changes in organs (fragments of organs), tissues and cells of patients, removed by surgery and (or) biopsy (operational biopsy material), as well as in tissues, organs and cells of a dead body during a postmortem examination.

2. Postmortem examination is carried out in order to determine the cause of death and clarify the diagnosis of the disease and to issue a document certifying the fact of death in the form approved by the authorized body.

3. Pathoanatomical diagnosis is based on the results of direct examination (macroscopic studies), studies using magnifying devices (microscopic studies), other technologies, as well as clinical and anatomical comparisons.

4. In the absence of suspicion of violent death, it is allowed to hand over a dead body without postmortem examination, except for cases of maternal, infant deaths or stillbirth.

In case of an unidentified direct cause of death, pathoanatomical diagnosis is carried out with the written consent of the spouse or a close relative or a legal representative.

5. At the request of the spouse, close relatives or legal representative of the deceased, the postmortem examination may be performed by an independent expert (experts) in the manner prescribed by the authorized body.

6. The state body for medical services (assistance) issues a pathologist's opinion on the cause of death and the diagnosis of the disease to the spouse, close relatives or legal representatives, and in their absence, to other relatives, as well as at the request of law enforcement agencies and (or) the court in the cases provided for in subparagraph 3) of paragraph 4 of Article 273 of this Code.

7. The standard for the organization of pathoanatomical diagnosis is developed and approved by the authorized body.

8. A postmortem report can be appealed in court by the spouse, close relative or legal representative of the deceased in the manner prescribed by the legislation of the Republic of Kazakhstan.

9. Postmortem examination is carried out with respect for the body of the deceased and the maximum preservation of its external anatomical forms.

### **Article 132. Conventional medicine. Healing**

1. Conventional medicine is a set of codified methods of prevention, diagnosis, treatment and rehabilitation, which are based on centuries-old traditions of traditional medicine and are approved for medical use.

2. Persons with medical education who have a certificate of a healthcare specialist and a license issued in accordance with the legislation of the Republic of Kazakhstan on permits and notifications are entitled to work in the field of conventional medicine.

3. Healing is a set of empirical information on healing methods, techniques, skills and their practical application in order to produce health effects.

4. It is prohibited to conduct healing sessions with the involvement of two or more persons, and also using the mass media.

5. A person who has caused harm to human health when applying healing methods is liable under the laws of the Republic of Kazakhstan.

### **Article 133. Assessment of health technologies**

1. The objects of health technology assessment are health technologies offered for use within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance or through other sources not prohibited by the legislation of the Republic of Kazakhstan.

2. The procedure for assessing health technologies and their application are determined by the authorized body.

### **Article 134. Rights of patients**

1. In addition to the rights specified in Chapter 12 of this Code, the patient has the right to :

1) respectful attitude in the process of prevention, diagnosis, treatment, respect for his/her cultural and personal values;

2) receive medical assistance in accordance with the priority determined solely on the basis of medical criteria, without the influence of any discriminatory factors;

3) select, replace a doctor or a medical facility providing medical assistance within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance, except for cases of emergency and urgent assistance;



4) be informed by a medical facility about audio and (or) video surveillance and recording ;

5) be relieved of suffering to the extent enabled by the current level of medical technologies;

6) obtain information (data on possible risks and benefits, proposed and alternative methods of treatment, information on possible consequences of refusing treatment, information on the diagnosis, prognosis and treatment plan in an intelligible form, and also explanation of the reasons for discharging him/her home or transferring to another medical facility), and an independent opinion on the state of his/her health, and a consultation;

7) obtain information on his/her rights and obligations, the services provided, the cost of paid services and the amount of co-payment, the procedure for their provision with account of their accessibility for persons with visual and (or) hearing impairments; the prescribed medicinal product; healthcare professionals providing medical services to him/her;

8) refuse to participate in the educational process, and also to refuse third parties to be present at medical and diagnostic procedures;

9) other rights provided for by the laws of the Republic of Kazakhstan.

2. Information on the patient's rights is placed on visual outreach boards of medical facilities.

3. Medical assistance is provided after obtaining the patient's informed consent to receive medical assistance. The informed consent of the patient during invasive interventions is drawn up in the form approved by the authorized body.

4. The patient can choose a person who shall be informed about the state of his/her health. With account of the state of the patient's health, information thereon can be hidden from the patient and communicated to the patient's spouse, close relatives or legal representatives.

5. Patients' rights are protected by state bodies, healthcare organizations, public associations within their competence.

### **Article 135. Obligations of patients**

1. In addition to the obligations specified in Chapter 12 of this Code, the patient is obliged :

1) to take measures to preserve and strengthen his/her health;

2) to show respect and tact in communication with healthcare professionals;

3) to provide a physician with all the information necessary for the diagnosis and treatment of the disease; after giving consent to medical intervention, to strictly follow the prescriptions of healthcare professionals;

4) to comply with internal regulations and take good care of the property of a medical facility, to cooperate with medical personnel when receiving medical assistance;

5) to promptly inform healthcare professionals on changes in his/her state of health in the process of diagnosis and treatment, as well as in cases of diseases that pose a danger to others, or suspicion of them;

6) not to commit acts that violate the rights of other patients;

7) to fulfill other obligations provided for by the laws of the Republic of Kazakhstan.

2. The obligations of patients specified in subparagraphs 2), 3) and 5) of paragraph 1 of this article apply to parents or other persons who care for a sick child in a hospital.

#### **Article 136. Right to refuse medical assistance**

1. The patient or his/her legal representative has the right to refuse medical assistance, except for the cases specified in Article 137 of this Code.

2. If medical assistance is denied, a healthcare professional explains possible consequences to the patient or his/her legal representative in an intelligible form.

3. Refusal of medical assistance with an indication of possible consequences is entered in medical records, also in electronic format, and signed by the patient or his/her legal representative, as well as by a healthcare professional.

If the patient or his/her legal representative refuses to sign their denial of medical assistance, it is necessary to make an appropriate entry in medical records, also in electronic format, which is signed by the healthcare professional.

4. If legal representatives of a minor or an incapacitated person refuse medical assistance necessary to save their lives, a medical facility has the right to apply to the guardianship and custody body and (or) the court to protect their interests.

#### **Article 137. Provision of medical assistance without the patient's consent**

1. The provision of medical assistance without the consent of the patient is allowed in relation to persons:

1) who are in a state of shock, in a comatose state, when they are unable to express their will;

2) with diseases that pose a danger to others;

3) with severe mental disorders (diseases);

4) with mental disorders (diseases) who committed a socially dangerous act.

2. Consent to the provision of medical assistance in relation to minors, except for the cases provided for by paragraph 2 of Article 78 of this Code, and consent for persons declared incapacitated by the court shall be given by their legal representatives.

3. The decision on the provision of medical assistance without consent in relation to the persons specified in paragraph 1 of this article shall be made by a case conference, and if it is impossible to gather required specialists - by a healthcare professional with subsequent notification of officials of a medical facility.

4. Medical assistance is provided without the consent of the patient until the grounds provided for in paragraph 1 of this article disappear.

#### **Article 138. Requirements for the development of standards for the provision of medical assistance**

1. Standard for the provision of medical assistance is a regulatory legal act establishing the requirements and rules for the processes of providing medical assistance in accordance with the legislation of the Republic of Kazakhstan in the field of healthcare.

2. The standard for providing medical assistance is developed for the profiles of diseases (services) and includes such requirements as:

- 1) general provisions;
- 2) the structure of facilities providing medical assistance;
- 3) the main tasks and areas of activities of facilities providing medical assistance;
- 4) the procedure for providing medical assistance in the context of levels, types, forms and conditions of its provision;
- 5) recommended staff;
- 6) recommended medical devices;
- 7) and others with account of the characteristics of the profile of the disease (service).

3. Standards for providing medical assistance are developed and approved by the authorized body.

#### **Chapter 17. DEPARTMENTAL MEDICINE**

#### **Article 139. Military-medical (medical) support of military personnel, cosmonaut candidates, cosmonauts, employees of special state and law enforcement agencies, their family members, retired law enforcement employees, and also citizens dismissed from military service, service in special state agencies**

1. Military-medical (medical) support is a set of measures, including the organization and provision of military-medical (medical) assistance, medical examinations, ensuring sanitary-epidemiological welfare, the supply of medicines and medical products, expertise in the field of healthcare, as well as scientific-methodological development and training in military medicine in the troops, units and departments of special state and law enforcement agencies in order to restore the combat capability and working capacity of personnel.

2. Military-medical (medical) support for military personnel, cosmonaut candidates, cosmonauts, employees of special state and law enforcement agencies, their family members, retired law enforcement employees, as well as citizens dismissed from military service, service in special state bodies, is carried out in accordance with the legislation of the Republic of Kazakhstan.

3. The procedure for organizing and conducting medical examinations, providing military-medical (medical) assistance, ensuring sanitary-epidemiological welfare, supplying

medicines and medical products in the Armed Forces of the Republic of Kazakhstan, other troops and military formations is established with account of the specifics of military service.

When providing medical assistance in the Armed Forces of the Republic of Kazakhstan, it is allowed to use medicines registered in the Republic of Kazakhstan and not included in the medicines formulary of military-medical institutions (organizations), the list of which is approved by the state body for defense.

4. The persons specified in paragraph 2 of this article have the right to receive medical assistance within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance in other healthcare entities in accordance with the legislation of the Republic of Kazakhstan.

#### **Article 140. Military-medical expertise**

1. Military-medical expertise is a type of medical activity, which is a set of scientific, methodological, organizational and practical measures carried out in order to optimally staff and improve medical support in the Armed Forces of the Republic of Kazakhstan, other troops and military formations of the Republic of Kazakhstan, special state and law enforcement agencies and to address other issues provided for by the legislation of the Republic of Kazakhstan.

2. Military-medical expertise is carried out in the Armed Forces of the Republic of Kazakhstan, other troops and military formations, special state and law enforcement agencies to:

1) determine the category of fitness of citizens for military service or service in special state and law enforcement agencies, as well as for battle assembly, training sessions of special state agencies or for the purposes of recording for health reasons;

2) establish the causal relationship of diseases, injuries (wounds, traumas, contusions) (hereinafter referred to as injuries) and death of citizens of the Republic of Kazakhstan in connection with their military service (performance of duties), service in special state and law enforcement agencies and battle assembly, training sessions of special state agencies;

3) determine the severity of injuries that did not entail disability, which were received by military personnel or employees in the performance of duties of service, military service (official duties);

4) identify psychophysiological qualities of the personality of citizens of the Republic of Kazakhstan joining special state and law enforcement agencies, their employees, as well as those joining state aviation, aviation personnel.

3. To conduct military-medical expertise, it is necessary to set up in-service and non-staff (regular and temporary) military-medical commissions under the Armed Forces of the Republic of Kazakhstan, other troops and military formations of the Republic of Kazakhstan, special state agencies and internal affairs bodies.

For special state agencies, the military-medical expertise is carried out by the military-medical commission of the national security bodies and the State Security Service of the Republic of Kazakhstan.

With regard to law enforcement agencies and the state courier service of the Republic of Kazakhstan, the military-medical expertise is carried out by the military-medical commission of the internal affairs bodies of the Republic of Kazakhstan.

To determine the degree of citizens' fitness for military service, regular medical commissions are set up in regions, cities of republican significance, the capital, towns and districts by decision of local executive bodies.

4. The procedure for conducting military-medical expertise, as well as the composition and powers of the military-medical expertise commission, are determined by the Rules for conducting military-medical expertise and the Regulations on the military-medical expertise commissions.

5. The category of citizens' fitness for military service in the Armed Forces of the Republic of Kazakhstan, other troops and military formations of the Republic of Kazakhstan, service, military service in special state and law enforcement agencies, as well as state aviation, is determined in the course of a medical examination.

When conducting a medical examination, it is necessary to apply the requirements for the state of health of citizens willing to serve in the Armed Forces of the Republic of Kazakhstan, other troops and military formations of the Republic of Kazakhstan, in special state and law enforcement agencies, as well as in state aviation.

#### **Article 141. Forensic medical, forensic psychiatric and forensic narcological examinations**

1. The procedural order for scheduling and producing forensic medical, forensic psychiatric and forensic narcological examinations is established by the Criminal Procedure Code of the Republic of Kazakhstan, the Civil Procedure Code of the Republic of Kazakhstan, the Administrative Offences Code of the Republic of Kazakhstan.

2. The procedure for organizing these types of forensic examinations and conducting forensic expert examinations is established by the legislation of the Republic of Kazakhstan on forensic expert examinations.

#### **Article 142. Provision of medical assistance to certain categories of civil servants and citizens of the Republic of Kazakhstan**

1. Medical assistance to certain categories of civil servants and citizens of the Republic of Kazakhstan is provided in accordance with the list approved by the Administrative Department of the President of the Republic of Kazakhstan in consultation with the Executive Office of the President of the Republic of Kazakhstan.

2. Medical assistance to persons specified in paragraph 1 of 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) using budgetary funds by types and in amounts determined by the Administrative Department of the President of the Republic of Kazakhstan.

3. Services for the provision of medical assistance in accordance with subparagraphs 1) and 2) of paragraph 2 of this article are paid for by the social health insurance fund.

4. The persons specified in paragraph 1 of this article have the right to receive medical assistance within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance in other healthcare entities.

**Article 143. Provision of medical persons, who are persons detained, taken into custody, placed in special institutions, held in pre-trial detention centers and institutions of the penal (penitentiary) system**

1. Medical care to persons, who are detained, taken into custody and placed in special institutions, shall be provided in accordance with the procedure, determined by the internal affairs bodies of the Republic of Kazakhstan in agreement with the authorized body.

2. Medical care to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system, shall be provided in accordance with the procedure, determined by the authorized body.

3. The persons specified in paragraphs 1 and 2 of this article shall exercise the rights of citizens of the Republic of Kazakhstan when receiving medical care, specified in subparagraphs 1), 2), 4), 5), 6), 7), 8) and 9) of paragraph 1 of article 134 of this Code.

4. Foreigners and stateless persons with restricted liberty, as well as those serving sentences in detention centers, detainees, who are taken into custody and placed in special institutions, have the right to receive a guaranteed volume of free medical care in accordance with the list and in the amount determined by the authorized body unless otherwise provided for by the laws of the Republic of Kazakhstan and international treaties ratified by the Republic of Kazakhstan.

**Footnote. Article 143 - as amended by the Law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.07.2022).**

**Article 144. Provision of medical assistance to athletes and coaches**

1. Medical support and medical assistance to athletes and coaches are provided in accordance with the rules for providing medical support and medical assistance to athletes and coaches during sports events, the recovery period after intense physical exertion, athletes' diseases and injuries, which are approved by the authorized body for physical culture and sports in consultation with the authorized body.

2. Athletes who failed to take a medical examination in accordance with the rules for medical examination of athletes for participation in sports competitions approved by the

authorized body for physical culture and sports in consultation with the authorized body are not allowed to participate in sports competitions.

3. Sports medicine organizations belong to healthcare organizations.

## **Chapter 18. REGULATION OF INDIVIDUAL RELATIONS IN THE FIELD OF HEALTHCARE**

### **Article 145. Procedure for surgical intervention, transfusion of blood, its components and the use of invasive diagnostic methods**

1. Surgical intervention, transfusion of blood, its components and the use of invasive diagnostic methods are implemented with the informed consent of patients.

Surgical intervention, transfusion of blood and its components, invasive diagnostic methods for persons with mental, behavioral disorders (diseases), recognized as incompetent by the court, and minors are carried out with the informed consent of their legal representatives.

2. Consent may be withdrawn, except for those cases when healthcare professionals have already started surgical intervention for health reasons and its termination is impossible due to the threat to the life and health of the patient.

3. In cases where a delay in performing a surgical intervention, transfusion of blood and its components, invasive diagnostic methods threatens the patient's life, and obtaining the consent of the patient or his/her legal representatives is impossible, the decision is taken by the attending physician or case conference who later inform the patient or his/her legal representatives on the measures taken.

### **Article 146. Assisted reproductive methods and technologies**

1. Assisted reproductive methods and technologies are methods of treating infertility (artificial insemination, artificial fertilization and embryo transfer), in the application of which some or all stages of conception and early development of embryos are carried out outside the mother's body (also using donor and (or) cryopreserved reproductive cells, tissues of reproductive organs and embryos, as well as surrogacy).

2. A woman and a man who are married have the right to use assisted reproductive methods and technologies with mutual informed consent to medical intervention.

3. A woman or a man who are not married have the right to use assisted reproductive methods and technologies given her (his) informed consent to medical intervention.

4. The procedure and conditions for applying assisted reproductive methods and technologies are determined by the authorized body.

5. When using assisted reproductive methods and technologies, it is not allowed to choose the sex of an unborn child, except for cases of possible inheritance of sex-related diseases.

6. The human embryo cannot be used for commercial, military or industrial purposes.

7. It is not allowed to export germ cells, human embryos from the Republic of Kazakhstan for commercial, military or industrial purposes.

#### **Article 147. Cloning**

Human cloning - the reproduction of genetically identical individuals - is prohibited in the Republic of Kazakhstan.

#### **Article 148. Donation of germ cells, tissues of reproductive organs**

1. Citizens of the Republic of Kazakhstan aged 18-35, physically and mentally healthy, who have undergone medical and genetic examination, have the right to be donors of germ cells, tissues of reproductive organs.

2. Donors have no right to information on further fate of their donor germ cells, tissues of reproductive organs.

3. The procedure and conditions for the donation of germ cells, tissues of reproductive organs are determined by the authorized body.

#### **Article 149. Use of contraception**

1. Citizens have the right to choose methods and means of contraception, including medical ones, as well as to refuse them.

2. Citizens are provided with medical assistance for the individual selection of acceptable methods and means of contraception, taking into account their health status, age and individual characteristics.

#### **Article 150. Artificial abortion**

1. A woman has the right to artificial abortion.

2. Artificial abortion at the request of a woman is performed at a gestational age of up to twelve weeks.

In order to prevent the artificial abortion, doctors are obliged to hold conversations aimed at clarifying the moral, ethical, psychological and negative physiological consequences, possible complications.

3. Artificial abortion for social reasons is performed at a gestational age of up to twenty-two weeks, and given medical indications and conditions that threaten the life of the pregnant woman and (or) the fetus (in the presence of monogenic genetic disorders, uncorrected congenital anomalies and fetal abnormalities incompatible with life) - regardless of the gestational age.

4. The performance of artificial abortion upon minors requires the consent of their parents or other legal representatives.



5. The performance of artificial abortion upon an adult recognized as legally incompetent, if she is incapable of expressing her will due to her condition, is possible by a court judgment taken at the request of her legal representative and with the participation of an adult recognized as legally incompetent.

6. At the request of a woman, medical facilities provide medical and social counseling before and after artificial abortion, including individual selection of methods and means of contraception.

7. The procedure for, the list of medical and social indications, as well as contraindications for artificial abortion are determined by the authorized body.

#### **Article 151. Surgical sterilization**

1. Surgical sterilization as a method of preventing unwanted pregnancy can be performed in relation to a patient who is at least thirty-five years old or has at least two children, and in the presence of medical indications and the consent of an adult citizen - regardless of the age and presence of children.

2. Surgical sterilization is performed only with the informed consent of the patient by healthcare entities licensed to carry out this activity, with mandatory prior notification of the irreversibility of this operation.

3. The procedure and conditions for carrying out surgical sterilization are determined by the authorized body.

#### **Article 152. Chemical castration**

1. Chemical castration is taking drugs by a patient that reduce sexual desire, which is performed in a medical facility on the basis of a court judgment.

2. The type of medicinal product used, the frequency of its administration within the period of validity of the compulsory medical measure 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.

**Footnote. Article 152 as amended by the Law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.07.2022).**

#### **Article 153. Determination of biological death, irreversible brain death. Conditions for the continuation, termination of artificial sustainment of functions of organs**

1. Biological death is the cessation of life processes in a living organism with complete loss of vital functions.

2. Biological death is determined by a healthcare professional given the combination of such symptoms as:

1) cardiac arrest;

2) respiratory arrest;

3) loss of functions of the central nervous system.

3. Irreversible brain death is the cessation of brain functions due to the death of the brain substance disabling any artificial sustainment of functions of organs.

4. Irreversible brain death is ascertained by a case conference of a medical facility on the basis of a combination of symptoms of cessation of the functions of the central nervous system, as well as clinical tests and other diagnostic studies in the manner prescribed by the authorized body.

5. Artificial sustainment of functions of organs continue if a person, whose irreversible brain death was diagnosed, during his/her lifetime agreed to the donation of organs (part of an organ) and (or) tissues (part of tissue) for transplantation.

In the absence of a person's living will, artificial sustainment of functions of organs can be continued in the case of the consent of the spouse, and in his (her) absence - the person's close relative, to the retrieval of organs (part of an organ) and (or) tissues (pieces of tissue) for transplantation.

6. It is allowed to stop artificial life support measures only in case of:

1) pronouncement of biological death;

2) irreversible brain death registered by a case conference, confirmed by necessary diagnostic and other studies in the manner prescribed by the authorized body, given written consent of the spouse, in his (her) absence - a close relative and (or) legal representative.

#### **Article 154. Euthanasia**

Euthanasia is prohibited in the Republic of Kazakhstan.

#### **Article 155. Anatomical gift**

1. Anatomical gift is voluntary donating by a capable person of his/her organs (parts of an organ) and (or) tissues (parts of tissue) both during life and after his/her death, which is documented as a duly executed contract or will of the person.

2. Information on the anatomical gift is not subject to disclosure.

3. In addition to bequeathed organs (parts of an organ) and (or) tissues (parts of tissue), an anatomical gift is also a dead body of an identified person, which is unclaimed for burial within twenty days of his/her death from a medical facility.

Unidentified dead bodies are not recognized as an anatomical gift.

4. The anatomical gift can be used for scientific, academic-research and educational purposes for biomedical studies.

5. The procedure and conditions for making and transferring the anatomical gift to healthcare organizations are determined by the authorized body.

#### **Article 156. Sex change**

1. Persons with gender identity disorders who have reached the age of twenty-one, are capable, except for persons with mental, behavioral disorders (diseases), have the right to change their sex.

2. The procedure for medical examination and sex reassignment for persons with gender identity disorders is determined by the authorized body.

## **Chapter 19. PROVISION OF MEDICAL ASSISTANCE IN CASE OF COMMON INFECTIOUS DISEASES**

### **Clause 1. Provision of medical-social assistance to persons with TB disease**

#### **Article 157. Provision of medical assistance to persons with TB disease**

1. The state guarantees persons with TB disease:

- 1) medical assistance and drug provision within the guaranteed volume of free medical care;
- 2) social and legal protection;
- 3) prevention of any forms of discrimination due to the nature of the disease;
- 4) the implementation of preventive measures to reduce the incidence of severe, acutely progressive TB forms among children.

2. Persons with active TB disease shall be subject to compulsory hospitalization, treatment and rehabilitation.

3. A person is recognized as having active TB disease on the basis of an opinion of a healthcare organization with account of the results of laboratory tests.

4. The procedure for conducting a medical examination to recognize a person as having active TB disease is determined by the authorized body.

5. A person recognized as having active TB disease may appeal against the decision of a healthcare organization in the manner prescribed by the laws of the Republic of Kazakhstan.

#### **Article 158. Grounds and procedure for referring persons with active TB disease for compulsory treatment**

1. Compulsory treatment of persons with TB disease includes treatment with anti-TB drugs and symptomatic treatment isolating patients in phthisiopulmonology organizations and is carried out within the framework of the guaranteed volume of free medical care.

2. The grounds for compulsory treatment of persons with TB disease are as follows:

1) refusal from treatment of a patient with active TB disease, which is entered in the patient's medical records;

2) unauthorized leave and violation of the treatment regimen in the form of unreasonable skipping of seven daily doses of anti-TB drugs during a calendar month, which is fixed in the patient's medical records.

3. Persons with TB disease who have undergone compulsory treatment, after being discharged from phthisiopulmonology organizations, shall register with a medical facility at their place of residence.

The rules for providing medical assistance to persons with TB disease referred for compulsory treatment are developed and approved by the authorized body.

4. At the request of healthcare organizations in accordance with the legislation of the Republic of Kazakhstan, a court shall take a judgment on compulsory treatment of persons with TB disease that evade treatment.

5. Persons with TB disease undergoing compulsory treatment enjoy all the rights of citizens of the Republic of Kazakhstan with restrictions related to the need to comply with the regime of stay in phthisiopulmonology organizations.

6. The job position of a person with TB disease who is referred for compulsory treatment is secured.

The time spent on compulsory treatment does not interrupt the length of service and is included in the total length of service.

7. Referral for compulsory treatment to a phthisiopulmonary organization does not entail a criminal record.

8. A person with TB disease referred for compulsory treatment, who lives in a dwelling of the state housing stock, shall retain dwelling for the entire period of being treated.

#### **Article 159. Social and legal protection of persons with TB disease or those who recovered from it**

1. Local executive bodies provide:

- 1) social support to persons with TB disease treated on an outpatient basis;
- 2) labor and household assistance to persons who recovered from TB disease.

2. Children with TB disease are allowed to study at school and other educational institutions on equal terms by decision of the central medical advisory commission of healthcare organizations providing phthisiopulmonary care.

3. The peculiarities of admission to, being in and dismissal from military service, service in special state and law enforcement agencies, courier service of persons with TB disease or who recovered from it are determined by the legislation of the Republic of Kazakhstan.

4. Persons disclosing information on persons who have fallen ill with and recovered from TB disease shall be liable under the laws of the Republic of Kazakhstan.

#### **Clause 2. Provision of medical-social assistance to persons infected with HIV**

#### **Article 160. Provision of medical assistance to persons infected with HIV**

1. The state guarantees persons infected with HIV:

1) accessible and good-quality confidential medical examination on a free basis, dynamic observation, provision of psychosocial, legal and medical advice;

2) medical assistance and drug provision within the guaranteed volume of free medical care;

3) implementation of preventive measures to reduce the risk of HIV transmission from a mother to her fetus and child;

4) social legal protection.

2. Citizens of the Republic of Kazakhstan, Candace, foreigners, stateless persons, refugees infected with HIV infection, permanently residing in the territory of the Republic of Kazakhstan, and children born to HIV-infected mothers with an unspecified diagnosis are subject to dynamic monitoring and provision of medicines within the guaranteed volume of free medical care.

3. Persons in need of pre-exposure and post-exposure prophylaxis of HIV infection are subject to medical observation and drug provision within the guaranteed volume of free medical care.

4. Persons infected with HIV, including foreigners and stateless persons with restricted liberty, serving a sentence in detention centers, detainees, who are taken into custody and placed in special institutions, have the right to receive a guaranteed volume of free medical care.

#### **Article 161. Social and legal protection of people infected with HIV**

1. Persons infected with HIV shall not be limited to training in educational institutions, stay in sanatorium-resort organizations and health-improving educational institutions.

2. Termination of an employment contract, a ban on conclusion of an employment contract, except for cases established by the labor legislation of the Republic of Kazakhstan, admission to educational organizations and social institutions, as well as infringement of the rights and legitimate interests of persons infected with HIV, as well as infringement of housing and other rights and interests of their close relatives.

3. It shall not be allowed for the employer to request the results of HIV testing, except for medical workers who have contact with blood, other biological fluids and biomaterials, subject to preliminary and periodic medical examinations.

4. If HIV infection is detected, employees with an established diagnosis of HIV infection shall be subject to transfer by the employer to another job, not related to the violation of the integrity of the skin or mucous membranes.

5. The specifics of admission, passage and dismissal from military service, service in special state and law enforcement agencies of persons infected with HIV shall be determined by the legislation of the Republic of Kazakhstan.

6. Persons who have become infected with HIV as a result of improper performance of their official duties by medical workers and workers in the field of consumer services have the right to compensation for harm caused to life or health, in accordance with the legislation of the Republic of Kazakhstan.

## **Article 162. HIV infection testing**

1. Citizens of the Republic of Kazakhstan, kandasses, foreigners, stateless persons, refugees and asylum seekers permanently and temporarily residing in the territory of the Republic of Kazakhstan have the right to voluntary anonymous and (or) confidential medical testing and counseling on HIV infection within the guaranteed volume of free medical care in public health organizations carrying out activities in the field of HIV infection prevention, in the manner determined by the authorized authority.

2. Obligatory confidential medical testing for HIV infection within the guaranteed volume of free medical care shall be subject to:

1) donors and recipients of blood, its components, organs (parts of organ) and (or) tissues (parts of tissue), sex cells;

2) persons on the basis of requests from the prosecution, investigation and (or) court;

3) persons for clinical and epidemiological indications in the manner determined by the authorized authority;

4) persons whose liberty is limited, who are serving a sentence by a court verdict in places of deprivation of liberty, taken into custody and placed in special institutions.

Obligatory confidential medical testing for HIV infection shall be carried out in public health organizations operating in the field of HIV infection prevention, in the manner determined by the authorized authority.

3. Medical testing for HIV infection of minors shall be carried out with the consent of their legal representatives or, at their request, incapacitated persons - with the consent of their legal representatives.

4. Employees of foreign diplomatic missions, employees of foreign consular offices and other persons who enjoy privileges and immunities in the Republic of Kazakhstan shall be tested for HIV only with their consent. The authorized authority shall preliminarily agree on a proposal on the need for their testing with the Ministry of Foreign Affairs of the Republic of Kazakhstan.

5. Health care organizations that have identified the fact of HIV infection during a medical testing, notify the examinee in writing about the result obtained, inform about the need to observe precautions aimed at protecting their own health and the health of others, and also warn about administrative and criminal liability for avoiding treatment and infecting others.

## **Chapter 20. PROVIDING MEDICAL CARE FOR MAJOR NON-COMMUNICABLE DISEASES**

### **Item 1. Provision of medical care in the field of mental health to persons with mental, behavioral disorders (diseases)**

### **Article 163. The rights of persons with mental, behavioral disorders (diseases)**

1. Persons with mental, behavioral disorders (diseases) have all the rights and freedoms of citizens provided by the Constitution of the Republic of Kazakhstan and this Code.

Restriction of exercise of the rights and freedoms of citizens associated with mental, behavioral disorders (diseases) shall be permissible only in cases provided by the laws of the Republic of Kazakhstan.

2. Persons with mental, behavioral disorders (diseases) in provision of medical care in the field of mental health have the right to:

1) receiving medical care in the field of mental health at the place of residence, as well as, if necessary, at the location;

2) refusal at any stage of treatment from the use of medical devices and methods, scientific research or educational process, from photography, video or filming;

3) invitation of a specialist involved in provision of medical care in the field of mental health (with the consent of the latter) to work in the medical commission;

4) receiving education according to the program of a general education school or a special school for children with intellectual disabilities, if the patient has not reached the age of eighteen;

5) conducting correspondence, receiving and sending parcels, postal packets, money, postal orders, using the telephone, receiving visitors, subscribing to periodicals;

6) possession of basic necessities and their acquisition, use of their own clothing;

7) a daily walk.

3. Persons with mental, behavioral disorders (diseases), in respect of whom compulsory medical measures shall be applied in psychiatric institutions of a specialized type with intensive supervision, have, in addition to the rights specified in Paragraphs 1 and 2 of this Article, the right to:

1) purchase of additional food;

2) receiving medical services in excess of the guaranteed volume of free medical care;

3) purchase of soft inventory, clothing, footwear;

4) use of long-distance telephone communication;

5) use of a cash control account.

The implementation of these rights shall be carried out at the expense of the person to whom they are granted.

### **Article 164. Protection of the rights and interests of persons with mental, behavioral disorders (diseases)**

1. Persons with mental, behavioral disorders (diseases) in provision of medical care in the field of mental health have the right to invite a representative of their choice to protect their

rights and legitimate interests. Registration of a representative office shall be carried out in the manner prescribed by the laws of the Republic of Kazakhstan.

2. The protection of the rights and legal interests of a minor or a person recognized by a court as incompetent shall be carried out by his legal representative.

3. Protection of the rights and legal interests of persons with mental, behavioral disorders (diseases) shall be carried out by their legal representatives.

4. A medical organization providing medical assistance in the field of mental health to persons with mental, behavioral disorders (diseases) shall provide the possibility of inviting a lawyer or legal representative, except for cases provided by Paragraph 5 of Article 166 of this Code.

#### **Article 165. Organization of medical care in the field of mental health for persons with mental, behavioral disorders (diseases)**

1. In order to organize medical care in the field of mental health to persons with mental, behavioral disorders (diseases), the state shall:

1) creates medical and production facilities and structural units for occupational therapy, training in new professions, as well as special production facilities, workshops or sites with facilitated working conditions for employment of persons with mental, behavioral disorders (diseases) in these organizations, including persons with disabilities;

2) ensure the organization and conduct of medical and social rehabilitation for persons with mental, behavioral disorders (diseases) at the place of residence, as well as, if necessary, at the location, at the request of the patient can be carried out anonymously.

2. Minors with mental, behavioral disorders (diseases), as well as persons recognized by the court as legally incompetent, medical and social rehabilitation shall be carried out with the consent of their legal representatives.

**Footnote. Article 165 as amended by the Law of the Republic of Kazakhstan dated 27.06.2022 № 129-VII (shall be enforced ten calendar days after the date of its first official publication).**

#### **Article 166. Psychiatric examination**

1. Psychiatric examination shall be carried out in order to establish mental, behavioral disorders (diseases) in the examined person, to determine the need for medical care in the field of mental health, as well as to resolve issues of custody, determine temporary disability, expertise of professional suitability, including during military medical expertise.

2. Psychiatric examination, as well as preventive examinations shall be carried out by a psychiatrist:

1) with the written consent of the examined person or upon the written application from his legal representatives indicating the reason for examination;



2) in relation to a minor or a person recognized by a court as incompetent, with the written consent of his legal representative;

3) when carrying out a military medical examination in accordance with the legislation of the Republic of Kazakhstan.

The data of the psychiatric examination and the conclusions on state of mental health of the examined person shall be recorded in medical records, which also indicate the reasons for contacting a psychiatrist and medical recommendations.

3. In case of objection or lack of consent of the examined person or the legal representative of the minor, the examination shall be carried out by decision of the custody and guardianship authority, which can be appealed to the court.

4. The doctor conducting the psychiatric examination shall be obliged to introduce himself to the examined person and his legal representative as a psychiatrist, except for the cases provided by Subparagraph 1) of Paragraph 5 of this Article.

5. A psychiatric examination of a person may be carried out without his consent or without the consent of his legal representative in the case when the examined person commits actions that give grounds to assume that he has a serious mental disorder (disease), which causes:

1) his immediate danger to himself and others;

2) his helplessness, that is, the inability to independently meet basic life needs in the absence of proper care;

3) significant harm to his health due to the deterioration of his mental state, if the person is left without medical assistance in the field of mental health.

6. A psychiatric examination of a person may be carried out without the consent of his legal representative, if the person being examined is under dynamic supervision in the manner prescribed by Paragraph 2 of Article 176 of this Code.

7. Psychiatric examination and psychiatric examination of a person shall be carried out in accordance with the legislation of the Republic of Kazakhstan.

8. In the cases provided by Paragraph 5 of this Article, the decision on psychiatric examination shall be made by the commission of psychiatrists with notification of legal representative of person.

9. The decision on a psychiatric examination of a person without his consent or without the consent of his legal representative, except for cases provided by Paragraph 6 of this Article, shall be made by a psychiatrist upon an application containing information on existence of grounds for such examination listed in Paragraph 5 of this Article.

10. The application for a psychiatric examination must be written, contain detailed information justifying the need for such an examination, and data on refusal of person (or his legal representative) to go to a psychiatrist. A psychiatrist has the right to request additional

information necessary for making a decision, having established that the application does not contain the circumstances provided by Paragraph 5 of this Article, or reasonably refuse in writing a psychiatric examination.

11. A minor or a person recognized by a court as incapable, placed in an organization providing medical care in the field of mental health to persons with mental, behavioral disorders (diseases), shall be subject to mandatory examination by the commission of psychiatrists in the manner prescribed by this Article.

12. During the first six months, a minor or a person declared legally incompetent by a court shall be subject to examination by the commission of psychiatrists at least once a month in order to resolve the issue of extending hospitalization. The decision to extend hospitalization for more than six months shall be made by a court decision on the basis of an appeal by the commission of psychiatrists in the manner prescribed by the legislation of the Republic of Kazakhstan in the field of healthcare.

13. If the commission of psychiatrists or the administration of an organization providing medical assistance in the field of mental health to persons with mental, behavioral disorders (diseases), abuses committed during hospitalization by legal representatives of a minor or a person declared incapable by a court, the administration of organization within twenty four hours from the moment of revealing the specified circumstances, notifies the prosecutor and the custody and guardianship authority at the place of residence of the ward.

#### **Article 167. Provision of medical care to persons with mental, behavioral disorders (diseases)**

1. The state guarantees:

1) emergency and routine medical care in the field of mental health within the guaranteed extent of free medical care;

2) psychiatric examination, determination of temporary disability;

3) social and household help and assistance in employment for persons with mental, behavioral disorders (diseases);

4) implementation of medical programs and measures aimed at ensuring equal opportunities for persons with special needs.

2. The diagnosis of a mental, behavioral disorder (disease) shall be established by a psychiatrist in accordance with the criteria of the international classification of diseases.

A primary health care doctor has the right to diagnose and treat borderline mental and behavioral disorders in the amount established by the authorized authority, with the patient's written consent. The conclusion of a doctor of primary health care shall not be a basis for restricting the rights and freedoms of a patient, as well as a psychiatric examination.

3. For the diagnosis and treatment of a person with a mental, behavioral disorder (disease), medical devices and methods shall be used, permitted by the legislation of the Republic of Kazakhstan in the field of healthcare.

4. Medicines and methods are used only for diagnostic and therapeutic purposes in accordance with the nature of painful disorders and are prohibited for use as punishment for a person.

5. The doctor, within forty-eight hours from the moment of the psychiatric examination, provides a person with a mental, behavioral disorder (disease), if he can correctly perceive the essence of the information presented, or his legal representative, written information about the nature of the mental, behavioral disorder (disease), goals and methods of treatment, as well as data on duration of the recommended treatment, possible pain, side effects, and expected results. The information provided shall be recorded in the medical records. In other cases, this information may be provided in accordance with Paragraph 4 of Article 273 of this Code.

6. Treatment of a person with a mental, behavioral disorder (disease) shall be carried out after obtaining his consent or his legal representative, except for the cases provided by Paragraph 7 of this Article.

7. Treatment can be carried out without the consent of a person with a mental, behavioral disorder (disease) or his legal representative only when applying compulsory medical measures on the grounds established by the laws of the Republic of Kazakhstan, as well as when compulsory hospitalization on the grounds provided by Paragraph 1 of Article 137 of this Code. In these cases, except for emergency hospitalization, treatment shall be carried out by the decision of the commission of psychiatrists. When a person is hospitalized without his consent, a decision on the procedure for treatment by the commission of psychiatrists must be ensured within forty-eight hours from the moment of his hospitalization.

8. A person with a mental, behavioral disorder (disease) or his legal representative has the right to refuse the proposed treatment or terminate it, except for the cases provided by Paragraph 7 of this Article.

9. The person who has refused treatment or his legal representative must be explained the possible consequences of termination of treatment. Refusal of treatment with indication of information about possible consequences shall be made out by an entry in the medical documentation signed by a person with a mental, behavioral disorder (disease) or his legal representative and a psychiatrist.

**Article 168. Hospitalization in a hospital of an organization providing medical care in the field of mental health to persons with mental, behavioral disorders (diseases)**

1. The grounds for hospitalization in a hospital shall be the presence of a person's mental, behavioral disorder (disease) and the decision of a psychiatrist on the need for examination or treatment in a hospital.

2. The hospitalization of a person in a hospital shall be carried out voluntarily at his request or with his written consent, except for the cases provided by Article 137 of this Code.

3. A minor shall be hospitalized in a hospital with the written consent of his legal representative.

4. In the event of an objection or the absence of a legal representative, hospitalization of a minor in a hospital shall be carried out by decision of the custody and guardianship authority, which can be appealed in court, with a written notification of the prosecutor within twenty-four hours from the date of the decision on hospitalization.

5. The consent of the person to hospitalization shall be formalized by an entry in the medical documentation signed by the person or his legal representative and the psychiatrist.

6. Compulsory hospitalization in a hospital shall be allowed on the basis of a court decision.

Compulsory hospitalization of a person in a hospital before a court makes a decision shall be allowed only in the cases provided by Subparagraphs 3) and 4) of Paragraph 1 of Article 137 of this Code.

For each case of involuntary hospitalization without a court decision, the administration of organization providing medical care in the field of mental health to persons with mental, behavioral disorder (disease), within forty-eight hours from the moment the person shall be placed in a hospital, sends a written notification to the prosecutor in accordance with the laws of the Republic of Kazakhstan, and also informs the spouse, close relatives and (or) legal representatives if there is information about them.

7. Stay of a person in a hospital forcibly continues only during the period of preservation of the grounds on which the hospitalization was carried out.

8. A person admitted to a hospital in a compulsory manner during the first six months shall be subject to examination by the commission of psychiatrists at least once a month in order to resolve the issue of extending hospitalization. The extension of hospitalization for more than six months shall be carried out by a court decision on the basis of an application by an organization providing medical assistance in the field of mental health to persons with mental, behavioral disorders (diseases), about the need to extend the period of compulsory hospitalization and treatment, to which the conclusion of the commission of psychiatrists shall be attached.

9. An extraordinary examination of a compulsorily hospitalized person may be carried out at the request of the patient himself or his legal representative.

A person hospitalized in a hospital on the grounds provided by Paragraph 1 of Article 137 of this Code shall be subject to compulsory examination within forty-eight hours from the moment of hospitalization by the commission of psychiatrists, which decides on the justification for hospitalization. In cases where hospitalization shall be recognized as unjustified and the hospitalized person does not express a desire to stay in the hospital, it shall be subject to immediate discharge.

10. In case of disagreement with compulsory hospitalization, a person with mental, behavioral disorder (disease) or his legal representative has the right to apply to the court in the manner prescribed by the laws of the Republic of Kazakhstan.

**Article 169. Discharge from hospital of organization providing medical care in the field of mental health to persons with mental, behavioral disorders (diseases)**

1. Discharge from the hospital shall be made after the person has recovered or his mental state has improved, when no further inpatient treatment shall be required, as well as upon completion of examination or expertise, which were the grounds for admission to the hospital.

2. Discharge of a person who is voluntarily in the hospital shall be made on his personal application, on application of his legal representative or by decision of his attending physician

3. Discharge of a person admitted to a hospital forcibly shall be made upon the conclusion of the commission of psychiatrists, a court decision or a prosecutor's order.

4. Discharge of a person to whom, according to a court ruling, compulsory measures of a medical nature were applied, shall be made only by ruling of the court.

5. A person admitted to a hospital voluntarily may be denied discharge if the commission of psychiatrists of organization providing medical care in the field of mental health to persons with mental, behavioral disorder (disease) establishes the grounds for compulsory hospitalization provided by Paragraph 1 of Article 137 of this Code. In this case, the issues of his stay in the hospital, prolongation of hospitalization and discharge from the hospital shall be resolved in the manner prescribed by Paragraphs 7 - 9 of Article 168 of this Code and Paragraph 3 of this Article.

**Article 170. Compulsory medical measures against a person with mental, behavioral disorders (diseases)**

1. Compulsory medical measures shall be applied by a court decision against a person with a mental, behavioral disorder (disease) who has committed socially dangerous acts, on the grounds and in the manner established by the legislation of the Republic of Kazakhstan.

2. Compulsory medical measures shall be carried out in organizations providing medical care in the field of mental health to persons with mental, behavioral disorder (disease), in the form of:

1) compulsory observation and treatment by a psychiatrist on an outpatient basis;

2) compulsory treatment in a general psychiatric hospital;

3) compulsory treatment in a psychiatric hospital of a specialized type;

4) compulsory treatment in a psychiatric hospital of a specialized type with intensive supervision.

3. A person admitted to a hospital for application of compulsory medical measures shall be recognized as incapable of work for the whole period of stay in the hospital.

4. Rules for use of funds from individuals and legal entities, including pension payments and state social benefits, credited to the cash control account of a state psychiatric organization of a specialized type with intensive supervision, for use by persons with mental,

behavioral disorders (diseases) who are on compulsory treatment shall be developed and approved by the authorized authority.

5. Accounting and reporting on use of funds of control account of cash of a state psychiatric organization of a specialized type with intensive supervision, as well as control over their use shall be carried out in accordance with the legislation of the Republic of Kazakhstan.

6. Protection of organization providing medical care in the field of mental health in the form of compulsory treatment of persons with mental, behavioral disorders (diseases) caused by use of psychoactive substances shall be assigned to the administration of this organization and shall be carried out in accordance with the legislation of the Republic of Kazakhstan in the field of security activities.

7. Protection of a state psychiatric organization 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 jointly with the authorized authority.

8. The equipment of a state psychiatric organization of a specialized type with intensive supervision with engineering and technical means of protection shall be carried out by the authorized authority in accordance with the procedure determined by the Ministry of Internal Affairs of the Republic of Kazakhstan jointly with the authorized authority.

#### **Article 171. Compulsory measures of medical nature against a person with mental, behavioral disorders (diseases) associated with use of psychoactive substances**

1. Compulsory medical measures shall be applied by a court decision in relation to a person with mental, behavioral disorders (diseases) associated with the use of psychoactive substances, who has committed a criminal offense, recognized in need of treatment, as well as against a person who has committed an administrative offense and evades voluntary treatment

2. Referral for compulsory treatment in organizations providing medical care in the field of mental health to persons with mental, behavioral disorders (diseases) shall not entail a criminal record.

The time spent on compulsory treatment shall not interrupt the length of service and shall be included in the total length of service.

3. For a person sent for compulsory treatment, living in a dwelling from the state housing stock, housing shall be retained for the whole period of being on treatment.

4. A person with a mental, behavioral disorder (disease) associated with the use of psychoactive substances who being under compulsory treatment has the right to:

1) become familiar with the internal regulations of organization for compulsory treatment and other documents regulating the procedure for staying in this organization;

2) maintain correspondence, receive and send parcels, small parcels, money, postal orders, use the telephone, receive visitors, subscribe to periodicals;

- 3) receive food, material and household and medical services;
- 4) labor in accordance with the labor legislation of the Republic of Kazakhstan;
- 5) purchase, at the expense of the funds in personal account, food and basic necessities, as well as other things that shall not be prohibited for storage and use on the territory of organization for compulsory treatment;
- 6) have meetings with close relatives in the manner prescribed by the internal regulations;
- 7) conduct correspondence without restriction;
- 8) receive packages, send and receive parcels in the manner determined by the internal regulations;
- 9) receive money transfers, which are credited to his personal account;
- 10) for a daily walk;
- 11) file complaints against actions (inaction) of employees of organizations to the authorized authority, prosecutor's office, court in the manner established by the laws of the Republic of Kazakhstan.

5. A person with a mental, behavioral disorder (disease) associated with the use of psychoactive substances who is under compulsory treatment in an organization shall be obliged to:

- 1) comply with the established internal regulations;
- 2) fulfill the legal requirements of administration of organization for compulsory treatment and medical personnel;
- 3) take the prescribed treatment;
- 4) take care of property of organization;
- 5) maintain cleanliness and order in organization for compulsory treatment, as well as carry out cleaning on its territory no more than two hours a week;
- 6) maintain personal hygiene.

#### **Article 172. Registration of a person with mental, behavioral disorder (disease) associated with use of psychoactive substances for compulsory treatment**

1. A person registered for compulsory treatment in connection with mental, behavioral disorder (disease) associated with use of psychoactive substances shall be notified of the date and place of medical examination by the organization providing medical assistance in the field of mental health.

The notice shall be sent by registered mail, telegram with acknowledgment of receipt.

2. A person duly notified by mental health care provider of the date and place of a medical examination (unless there are valid reasons) and evading a medical examination on the basis of a reasoned opinion of mental health care provider shall be subject to brought by the internal affairs authorities for compulsory examination.

3. The bringing shall be carried out by compulsory escorting the person evading medical examination to the place of compulsory examination for a period not exceeding three hours only on working days from nine to eighteen hours.

4. The following shall be recognized as valid reasons for a person's failure to appear for a medical examination: illness that makes it impossible for him to appear, death of close relatives, natural disasters, and other reasons that make it impossible to appear at the appointed time. The escorted person shall be obliged to notify the initiator of compulsory bringing about the existence of valid reasons preventing the appearance of the summons at the appointed time.

5. The conclusion on bringing shall be announced to the person subject to the bringing before its execution, which shall be certified by his signature on conclusion.

In case of refusal of the forwarded person to sign, a note shall be made in conclusion.

**Article 173. Organization of compulsory treatment of a person with mental, behavioral disorder (disease) associated with use of psychoactive substances**

1. A person with mental, behavioral disorder (disease) associated with use of psychoactive substances who is under compulsory treatment in organization providing medical care in the field of mental health has all the rights and freedoms of citizens provided by the Constitution of the Republic of Kazakhstan.

2. Restrictions on exercise of the rights and freedoms of a person with mental, behavioral disorder (disease) associated with use of psychoactive substances undergoing compulsory treatment in an organization providing medical care in the field of mental health shall be permissible only in cases provided by the laws of the Republic of Kazakhstan.

3. A person with mental, behavioral disorder (disease) associated with use of psychoactive substances, who is under compulsory treatment in an organization providing medical care in the field of mental health, shall be provided with work at his request, he shall be subject to the labor legislation of the Republic of Kazakhstan.

4. During the period of compulsory treatment in organization providing medical care in the field of mental health, the time of compulsory hospitalization for examination shall be counted.

5. The conditions of detention of a person with mental, behavioral disorder (disease) associated with use of psychoactive substances for compulsory treatment in an organization providing medical assistance in the field of mental health shall be established by the internal regulations approved by the authorized authority.

6. A person with mental, behavioral disorder (disease) associated with use of psychoactive substances, who is under compulsory treatment in organization providing medical care in the field of mental health to persons with mental, behavioral disorders (diseases), violating the internal regulations of procedure or avoiding treatment, shall be placed in a special ward if his actions threaten the life and health of others or personally to him. Placement in a special ward



shall be carried out by written order of the head of organization providing medical care in the field of mental health, for a period of up to ten days, with a notification from the prosecutor within twenty-four hours from the moment the person shall be placed. In the absence of the head at the workplace, the decision to be placed in a special ward shall be made by the senior employee of the organization providing mental health care, with subsequent informing the head, who determines by written order the terms of detention in the special ward.

7. Unauthorized leave of a person with mental, behavioral disorder (disease) associated with use of psychoactive substances from organization providing medical care in the field of mental health, as well as failure to arrive at the organization by the established date, are evasion of treatment and entail liability in accordance with the laws Republic of Kazakhstan. His delivery for compulsory treatment shall be carried out by the internal affairs authorities of the Republic of Kazakhstan on the basis of a court order.

The period of unauthorized absence of a person with mental, behavioral disorder (disease) associated with use of psychoactive substances in organization providing medical care in the field of mental health shall not be included in the treatment period.

8. For committing offenses and (or) causing material damage, a person with mental, behavioral disorder (disease) associated with use of psychoactive substances, who is under compulsory treatment in organization providing medical assistance in the field of mental health, shall be liable as established by the laws of the Republic of Kazakhstan.

**Article 174. Discharge of a person with mental, behavioral disorder (disease) associated with use of psychoactive substances from organization providing medical care in the field of mental health**

1. A person with mental, behavioral disorder (disease) associated with use of psychoactive substances, terminates compulsory treatment and shall be discharged from organization providing medical care in the field of mental health:

- 1) upon expiration of the period of compulsory treatment determined by the court;
- 2) in connection with the identification of concomitant serious diseases that impede the implementation of compulsory treatment, by a court order;
- 3) ahead of schedule in connection with a successful cure, but not earlier than six months, by court order.

2. If a person with mental, behavioral disorder (disease), associated with use of psychoactive substances, who is in organization providing medical care in the field of mental health, avoids treatment, the period of stay may be extended by a court decision on the basis of a request from the administration of organization providing medical care in the field of mental health based on medical opinion, but for no more than one year. In this case, the time spent in an organization providing medical care in the field of mental health should not exceed two years.

3. A person discharged from an organization providing medical care in the field of mental health shall be returned documents, money and things seized and stored in the organization's storage room.

4. The working conditions of persons with mental, behavioral disorder (disease) associated with use of psychoactive substances shall be determined by the labor legislation of the Republic of Kazakhstan.

5. The administration of organization providing medical care in the field of mental health shall notify the local executive authority at the place of residence about persons become free from the organization providing medical care in the field of mental health to provide assistance in the household and work arrangement and to the healthcare organization at the place of residence to ensure surveillance.

6. Persons who have undergone compulsory treatment, after being discharged from an organization providing medical assistance in the field of mental health, except for those discharged by a court order as recovered early, shall be obliged to register with an organization providing medical assistance in the field of mental health to persons with mental, behavioral disorders (diseases), at the place of residence and undergo supportive treatment in it in the manner determined by the authorized authority.

In case of evasion of registration and undergoing supportive treatment, the person may be forced to be brought by the internal affairs authority.

7. Labor and household arrangements of a person discharged from an organization providing medical care in the field of mental health shall be carried out at the place of residence and shall be assigned to local executive authorities.

#### **Article 175. Safety measures in providing medical care in the field of mental health**

1. Medical care in the field of mental health in inpatient conditions shall be carried out in the least restrictive conditions that ensure the safety of the hospitalized person and other persons, subject to medical personnel observing their rights and legitimate interests.

2. Measures of physical restraint and isolation during compulsory hospitalization and hospitalization shall be applied only in those cases, forms and for that period of time when, in the opinion of the psychiatrist, it is impossible to prevent the actions of the hospitalized person posing an immediate danger to him or others by other methods persons, and shall be carried out under the constant supervision of medical personnel. The forms and time of application of measures of physical restraint or isolation shall be recorded in medical records with notification of his legal representative.

3. Law enforcement officers shall be obliged to assist medical workers in the implementation of compulsory examination, compulsory hospitalization, to ensure safe conditions for access to the hospitalized person for the purpose of his examination, as well as in cases that threaten the life and health of others from the hospitalized person (person subject to hospitalization).

## **Article 176. Dynamic observation of persons with mental, behavioral disorders (diseases)**

1. Dynamic observation of persons with mental, behavioral disorders (diseases) may be established regardless of the consent of the person with mental, behavioral disorder (disease) or his legal representative in the cases provided by Paragraph 2 of this Article, and involves monitoring the state of mental health of the person by regular examinations by a psychiatrist and providing him with the necessary medical and social assistance.

2. Dynamic observation can be established for a person suffering from a chronic or protracted disorder with severe, persistent, often exacerbated painful manifestations.

3. Rules of dynamic observation, as well as termination of dynamic observation of persons with mental, behavioral disorders (diseases) shall be developed and approved by the authorized authority.

4. When the mental state changes, a person with mental, behavioral disorders (diseases) may be examined without his consent or without the consent of his legal representative on the grounds and in the manner provided by Paragraph 5 of Article 166 of this Code. Dynamic observation of persons with mental, behavioral disorders (diseases) can be resumed in such cases by the decision of the commission of psychiatrists.

## **Item 2. Providing medical care for orphan diseases**

### **Article 177. Providing medical care for orphan diseases**

1. Orphan (rare) diseases include rare serious diseases that threaten human life or lead to disability, the frequency of which does not exceed the officially defined level.

2. Treatment of orphan diseases shall be carried out within the guaranteed capacity of free medical care.

3. The list of orphan diseases and medicines for their treatment (orphan) shall be approved by the authorized authority, taking into account the following criteria:

- 1) prevalence in the Republic of Kazakhstan;
- 2) the need for systematic treatment, for which there are medicines (curable patients) developed and registered on the territory of the Republic of Kazakhstan;
- 3) the need for systematic treatment with use of medicines that shall be developed and available in the world, but shall not be registered for use on the territory of the Republic of Kazakhstan;
- 4) the presence of diseases for treatment of which there are no developed medicines in the world;
- 5) the need to provide palliative care due to the lack of radical therapy (incurable patients)

4. The rules for formation of the list of orphan diseases and medicines for their treatment shall be developed and approved by the authorized authority.

## **Chapter 21. TEMPORARY ADAPTATION AND DETOXIFICATION CENTERS**

### **Article 178. Temporary adaptation and detoxification centers**

1. Temporary adaptation and detoxification centers shall be created by decision of local executive authorities.

2. The procedure for organizing the activities of temporary adaptation and detoxification centers and the internal regulations of temporary adaptation and detoxification center shall be determined by the authorized authority in agreement with the Ministry of Internal Affairs of the Republic of Kazakhstan.

### **Article 179. Grounds for placing persons in temporary adaptation and detoxification centers**

The basis for placing persons in temporary adaptation and detoxification centers shall be the conclusion of a medical examination of the person being placed in a state of alcohol inebriation (intoxication), carried out by the staff of an organization providing medical care in the field of mental health.

### **Article 180. Reception and registration of persons placed in temporary adaptation and detoxification centers**

1. The procedure for admitting and registering persons placed in temporary adaptation and detoxification centers, for conducting a personal examination, medical examination, as well as a list of things subject to seizure, shall be determined in accordance with the rules for organizing the activities of temporary adaptation and detoxification centers.

2. Close relatives at the place of residence shall be immediately notified of the placement in temporary adaptation and detoxification center of persons in a state of alcohol inebriation (intoxication).

When a foreigner is placed in a temporary adaptation and detoxification center, the medical personnel shall notify the General Prosecutor's Office of the Republic of Kazakhstan, the Ministry of Foreign Affairs of the Republic of Kazakhstan, the National Security Committee of the Republic of Kazakhstan and the Ministry of Internal Affairs of the Republic of Kazakhstan.

### **Article 181. Regimen of detention in temporary adaptation and detoxification centers**

1. In temporary adaptation and detoxification centers, a regime shall be established that ensures the safety of detainees and excludes the possibility of their unauthorized leave. The conditions of detention, the requirements for the equipment of the premises shall be determined by the internal regulations of temporary adaptation and detoxification center.

2. Men placed in temporary adaptation and detoxification centers shall be placed separately from women.

3. Minors placed in temporary adaptation and detoxification centers shall be hospitalized in the specialized departments of the relevant medical organization with the consent of their legal representatives.

4. Persons with infectious and parasitic diseases may not be kept with other persons placed in temporary adaptation and detoxification centers.

#### **Article 182. Rights and obligations of persons placed in temporary adaptation and detoxification centers**

1. Persons placed in temporary adaptation and detoxification centers have the right:

1) receive information about their rights and obligations, the regime of detention;

2) personal safety while in temporary adaptation and detoxification center;

3) receive material and household and medical and sanitary services;

4) apply to the medical personnel of organization providing medical care in the field of mental health, as well as to the police, prosecutor's office, and the court on issues of violation of their rights and legal interests.

2. Persons placed in temporary adaptation and detoxification centers shall be obliged to comply with the internal regulations of the temporary adaptation and detoxification center, approved by the authorized authority in agreement with the Ministry of Internal Affairs of the Republic of Kazakhstan.

#### **Article 183. Releasing persons placed in temporary adaptation and detoxification centers**

1. Persons placed in temporary adaptation and detoxification centers shall be subject to immediate release in a planned manner upon achieving an improvement in their condition that does not require further observation and treatment in the center, within 24 hours from the date of admission.

2. The released persons shall be returned against receipt the documents, money and things confiscated from them for storage, except for things the storage of which is illegal.

3. In case of illegal storage by persons placed in temporary adaptation and detoxification centers, firearms or cold weapons, explosive, potent or poisonous substances, narcotic drugs, psychotropic substances and their precursors, decisions shall be made in accordance with the legislation of the Republic of Kazakhstan.

4. Upon discharge, the person shall be issued a certificate of his stay in temporary adaptation and detoxification center.

#### **Chapter 22. NATIONAL PREVENTIVE MECHANISM**

**Footnote.** In Chapter 22, the words "Commissioner for Human Rights", "Commissioner for Human Rights", "of Commissioner for Human Rights", "by Commissioner for Human Rights", "to Commissioner for Human Rights" are replaced, respectively, by the words "

Commissioner for Human Rights in the Republic of Kazakhstan", "Commissioner for Human Rights in the Republic of Kazakhstan", "of Commissioner for Human Rights in the Republic of Kazakhstan", "by Commissioner for Human Rights in the Republic of Kazakhstan", "to Commissioner for Human Rights in the Republic of Kazakhstan" in accordance with the Law of the Republic of Kazakhstan dated 05.11.2022 № 157-VII (shall be enforced ten calendar days after the date of its first official publication).

#### **Article 184. National preventive mechanism**

1. The National preventive mechanism operates as a system for prevention of torture and other cruel, inhuman or degrading treatment or punishment, functioning through the activities of participants in the national preventive mechanism.

2. As part of their activities, the participants of the national preventive mechanism visit organizations for compulsory treatment (specialized anti-tuberculosis organizations, organizations providing medical care in the field of mental health, for use of compulsory medical measures (for compulsory treatment - a general psychiatric hospital, a specialized psychiatric hospital), a psychiatric hospital of a specialized type with intensive supervision) and other organizations determined by the laws of the Republic of Kazakhstan for visiting by these participants.

3. Participants of the national preventive mechanism shall be the Commissioner for Human Rights in the Republic of Kazakhstan, as well as members of public oversight commissions and public associations selected by the Coordination Council, carrying out activities to protect the rights and legal interests of citizens of the Republic of Kazakhstan, lawyers, social workers, doctors.

4. The Commissioner for Human Rights in the Republic of Kazakhstan coordinates the activities of the participants in the national preventive mechanism, takes measures in accordance with the legislation of the Republic of Kazakhstan to ensure the necessary potential and professional knowledge of the participants in the national preventive mechanism

5. Reimbursement of expenses of participants of the national preventive mechanism for preventive visits shall be carried out from budget funds in the manner determined by the Government of the Republic of Kazakhstan.

#### **Article 185. Coordination Council**

1. In order to ensure effective coordination of the activities of the national preventive mechanism, a Coordination Council shall be established under the Commissioner for Human Rights in the Republic of Kazakhstan.

The members of the Coordination Council, except for the Ombudsman, shall be elected by the commission created by the Ombudsman from among the citizens of the Republic of Kazakhstan.

2. The Commissioner for Human Rights in the Republic of Kazakhstan approves:

- 1) regulations on the Coordination Council under the Commissioner for Human Rights in the Republic of Kazakhstan;
- 2) rules for selection of participants in the national preventive mechanism;
- 3) rules for formation of groups of members of the national preventive mechanism for preventive visits;
- 4) guidelines for preventive visits;
- 5) rules for preparation of the annual consolidated report on the results of preventive visits

3. The Coordination Council works with the Subcommittee on Prevention of Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment of the United Nations Committee against Torture.

#### **Article 186. Requirements for participants in the national preventive mechanism**

1. Participants of the national preventive mechanism cannot be persons:

- 1) having an outstanding or unexpunged conviction in the manner prescribed by the law of the Republic of Kazakhstan;
- 2) suspects or accused of committing a criminal offense;
- 3) recognized by the court as incapable or partially incapacitated;
- 4) judges, lawyers, civil servants and military personnel, as well as employees of law enforcement and special state authorities;
- 5) registered with organization providing medical care in the field of mental health.

2. Participants of the national preventive mechanism also cannot be persons released from criminal liability on the basis of Paragraphs 3), 4), 9), 10) and 12) of part one of Article 35 or Article 36 of the Criminal Procedure Code of the Republic of Kazakhstan for committing an intentional crime; dismissed from the state or military service, from law enforcement and special state authorities, courts or excluded from the bar for negative reasons; deprived of a license to practice law.

#### **Article 187. The rights of a participant in the national preventive mechanism**

1. A participant in the national preventive mechanism has the right:

- 1) receive information on the number of persons held in organizations subject to preventive visits, the number of such organizations and their location;
- 2) have access to information regarding the treatment of persons held in organizations subject to preventive visits, as well as the conditions of their detention;

- 3) carry out preventive visits in the prescribed manner as part of the formed groups;
  - 4) conduct interviews with persons detained in organizations subject to preventive visits and (or) their legal representatives without witnesses, personally or, if necessary, through an interpreter, as well as with any other person who, in the opinion of the participant of the national preventive mechanism, can provide relevant information;
  - 5) freely select and visit organizations subject to preventive visits;
  - 6) receive messages and complaints about the use of torture and other cruel, inhuman or degrading treatment or punishment.
2. A participant in the national preventive mechanism shall be independent in carrying out legal activities.

#### **Article 188. Obligations of a participant in the national preventive mechanism**

1. When exercising his powers, a participant of the national preventive mechanism shall be obliged to comply with the legislation of the Republic of Kazakhstan.
2. Interference of a participant of the national preventive mechanism in the activities of organizations subject to preventive visits shall not be allowed.
3. If there are circumstances that raise doubts about the impartiality of a participant in the national preventive mechanism, who is a member of the preventive visit group, he must refuse to participate in the preventive visit.
4. A participant in the national preventive mechanism shall be obliged to register received messages and complaints about the use of torture and other cruel, inhuman or degrading treatment or punishment in the manner determined by the Commissioner for Human Rights in the Republic of Kazakhstan.  
Received messages and complaints shall be forwarded to the Commissioner for Human Rights in the Republic of Kazakhstan in the manner prescribed by the legislation of the Republic of Kazakhstan.  
Information about received and transmitted messages and complaints shall be included in the report on the results of preventive visits.
5. A participant of the national preventive mechanism who has violated the provisions of this Code shall bear responsibility established by the laws of the Republic of Kazakhstan.

#### **Article 189. Termination of powers of a participant of the national preventive mechanism**

The powers of a participant in the national preventive mechanism shall be terminated when:

- 1) violation of the provisions of this Code;
- 2) a written statement of resignation;
- 3) his death or the entry into force of a 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 legal force of the judgment of the court;
- 7) the occurrence of other cases provided by the laws of the Republic of Kazakhstan.

#### **Article 190. Types and periodic of preventive visits**

1. Preventive visits to participants in the national preventive mechanism shall be divided into:

- 1) periodic preventive visits carried out on a regular basis at least once every four years;
- 2) intermediate preventive visits carried out in the period between periodic preventive visits in order to monitor the implementation of recommendations based on the results of the previous periodic preventive visit, as well as to prevent the persecution of persons with whom the participants of the national preventive mechanism had interviews by the administration of organization subject to the preventive visit;
- 3) special preventive visits carried out on the basis of received reports of torture and other cruel, inhuman or degrading treatment or punishment.

2. The Coordination Council determines the time frame and list of organizations subject to preventive visits within the allocated budgetary funds.

#### **Article 191. Procedure for preventive visits**

1. Preventive visits shall be conducted by groups formed by the Coordination Council from the participants of the national preventive mechanism, in the manner determined by the Government of the Republic of Kazakhstan in agreement with the Ombudsman.

2. When forming groups for preventive visits, none of the participants in the national preventive mechanism may be subjected to any discrimination on the basis of origin, social, official and property status, sex, race, nationality, language, attitude to religion, beliefs, place of residence or any other circumstances.

3. Ensuring the safety of the participants in the national preventive mechanism shall be the responsibility of the administration of organization subject to the preventive visit. In case of illegal actions of the participants of the national preventive mechanism, the head of the administration of organization subject to the preventive visit shall inform the Commissioner for Human Rights in the Republic of Kazakhstan in writing.

4. Based on the results of each preventive visit, on behalf of the group, a written report shall be drawn up in the form approved by the Coordination Council, which shall be signed by all members of the group that carried out the preventive visit. A member of the group with a dissenting opinion shall draw up it in writing and attach it to the report.

#### **Article 192. Annual consolidated report of participants of the national preventive mechanism**

1. The Coordination Council prepares an annual consolidated report of participants of the national preventive mechanism, taking into account their reports on the results of preventive visits.

2. The annual consolidated report of participants in the national preventive mechanism shall also include:

1) recommendations to authorized state authorities to improve the conditions for treatment of persons held in organizations subject to preventive visits and to prevent torture and other cruel, inhuman or degrading treatment or punishment;

2) proposals for improving the legislation of the Republic of Kazakhstan.

A financial report on preventive visits for the past year shall be attached to the annual consolidated report of participants in the national preventive mechanism.

3. The annual consolidated report of participants of the national preventive mechanism shall be sent for consideration to the authorized state authorities and posted on the Internet resource of the Ombudsman no later than one month from the date of its approval by the Coordination Council.

#### **Article 193. Confidentiality**

1. Participants of the national preventive mechanism shall not have the right to disclose information about the private life of a person that became known to them during preventive visits, without the consent of this person.

2. Disclosure by the participants of the national preventive mechanism of information about the private life of a person, which became known to them in the course of preventive visits, without the consent of this person shall entail responsibility established by the laws of the Republic of Kazakhstan.

#### **Article 194. Interaction of authorized state authorities with participants in the national preventive mechanism**

1. State authorities and their officials shall assist the participants of the national preventive mechanism in carrying out their legal activities.

No state authority or official has the right to restrict the rights and freedoms of citizens of the Republic of Kazakhstan for informing the participants of the national preventive mechanism about the use of torture and other cruel, inhuman or degrading treatment and punishment.

Officials who obstruct the legal activities of the participants of the national preventive mechanism shall bear responsibility established by the laws of the Republic of Kazakhstan.

2. The authorized state authorities, within three months from the date of receipt of the annual consolidated report of the participants of the national preventive mechanism, shall

inform the Commissioner for Human Rights in the Republic of Kazakhstan in writing about the measures taken following the consideration of the reports received.

3. Based on the reports of the participants of the national preventive mechanism based on the results of preventive visits, the Commissioner for Human Rights in the Republic of Kazakhstan, in the manner prescribed by the legislation of the Republic of Kazakhstan, has the right to apply to authorized state authorities or officials with a petition to initiate disciplinary or administrative proceedings or a criminal case against an official who has violated rights and freedoms of a person and a citizen of the Republic of Kazakhstan.

## **Chapter 23. SCOPE OF MEDICAL CARE**

### **Article 195. Scope of medical care**

Medical care shall be provided in the following scope:

1) the minimum, which is a guaranteed amount of free medical care provided in accordance with Article 196 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 scope of medical care, including medical care:

within the framework of voluntary and (or) imputed medical insurance provided at the expense of contributions of individuals and legal entities;

provided through the provision of paid services and other sources not prohibited by the legislation of the Republic of Kazakhstan;

provided to military personnel, candidates for astronauts, cosmonauts, employees of special state and law enforcement agencies, members of their families, pensioners of law enforcement agencies, persons dismissed from military service, service in special state authorities, as well as certain categories of civil servants and citizens of the Republic of Kazakhstan in the military and medical (medical) institutions (organizations) at the expense of the funds provided by the legislation of the Republic of Kazakhstan;

provided to persons, held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of funds provided for by the legislation of the Republic of Kazakhstan;

provided to individuals at the expense of one-time pension payments in accordance with the legislation of the Republic of Kazakhstan.

The program of guarantees of medical care within the guaranteed volume of free medical care and medical care in the system of compulsory social health insurance is determined annually by the Government of the Republic of Kazakhstan for a three-year period.

**Footnote. Article 195 as amended by the Law of the Republic of Kazakhstan dated 02.01.2021 № 399-VI (shall be enforced from 01.01.2021); dated 30.12.2021 № 95-VII (shall**

be enforced from 01.07.2022); dated 19.04.2023 № 223-VII (for the procedure of entry into force, see Article 3).

## **Article 196. Guaranteed scope of free medical care**

1. The guaranteed volume of free medical care is provided to citizens of the Republic of Kazakhstan, Candas, refugees, foreigners and stateless persons permanently residing in the territory of the Republic of Kazakhstan at the expense of budgetary funds, includes preventive , diagnostic and curative medical services with the greatest proven effectiveness, as well as drug provision.

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

Foreigners and stateless persons temporarily staying in the Republic of Kazakhstan, asylum seekers have the right to receive a guaranteed scope of free medical care for diseases that pose a danger to others, according to the list and in the amount determined by the authorized authority, unless otherwise provided by the laws of the Republic Kazakhstan or international treaties ratified by the Republic of Kazakhstan.

2. Medical care included in the guaranteed scope 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 scope of free medical care includes:

1) emergency medical care;

2) primary health care;

3) specialized medical care on an outpatient basis:

in provision of services for prevention and diagnosis of HIV infection and tuberculosis;

in case of injury, poisoning or other emergency conditions;

with socially significant diseases;

for chronic diseases subject to dynamic observation, according to the list determined by the authorized authority;

4) specialized medical care in hospital-replacing conditions:

with socially significant diseases;

for chronic diseases subject to dynamic observation, according to the list determined by the authorized body;

5) specialized medical care in stationary conditions:

when isolating persons who were in contact with a sick infectious or parasitic disease that poses a danger to others, as well as bacteria carriers, virus carriers and persons with suspected infectious or parasitic disease posing a danger to others, according to the list determined by the authorized authority;

in treatment of infectious, parasitic diseases and diseases that pose a danger to others, according to the list determined by the authorized authority;

in an emergency form for persons who are not consumers of services in the system of compulsory social health insurance, including carrying out medical and diagnostic measures in the admission department of a round-the-clock hospital until a diagnosis shall be established that does not require treatment in a round-the-clock hospital, according to the list determined by the authorized authority;

in a planned form according to the list of diseases determined by the authorized authority;

6) medical rehabilitation in treatment of the underlying disease, as well as medical rehabilitation of patients with tuberculosis;

7) palliative medical care according to the list of diseases determined by the authorized authority;

8) provision of blood products and blood components;

9) pathological diagnostics;

10) preparation of a posthumous donor for removal of organs (part of organ) and (or) tissues (part of tissue), removal, conservation, procurement, storage, transportation of organs (part of organ) and (or) tissues (part of tissue) for the purpose of organ transplantation (part of organ) and (or) tissues (parts of tissue).

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

1) in provision of ambulance, as well as specialized care, including high-tech medical services, in inpatient and inpatient substitution conditions in accordance with the medicinal formulations of healthcare organizations;

2) in provision of primary health care in accordance with the list of diseases against which preventive vaccinations shall be carried out;

3) in provision of primary health care and specialized care on an outpatient basis in accordance with the list of medicines and medical devices for free and (or) preferential provision of certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions).

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

It shall be allowed to use medicines and unregistered medical devices that are not registered in the Republic of Kazakhstan and are not included in the Kazakhstan National Medicinal Formulary to provide health care for a specific patient or to provide medical care to a limited contingent of patients with rare (orphan) diseases and (or) conditions in accordance with the procedure determined by the authorized body.

**Footnote. Article 196 as amended by the Law of the Republic of Kazakhstan dated 03.01.2022 № 101-VII (shall be enforced upon expiry of sixty calendar days from the date of its first official publication).**

## **Article 197. Principles for formation of the guaranteed scope of free medical care**

1. The guaranteed scope of free medical care shall be formed on the basis of the principles of universality, accessibility, evidence, realism and regulation.

2. The principle of universality implies universal and equal coverage of the minimum volume of medical care, regardless of the level of income and social status of the persons specified in Paragraph 1 of Article 196 of this Code.

3. The principle of accessibility lies in the possibility of receiving by the persons specified in Paragraph 1 of Article 196 of this Code the guaranteed scope of free medical care in the territory of the Republic of Kazakhstan.

4. The principle of evidence implies the availability of proven scientific and clinical data on effectiveness and safety of medical services, drugs and medical devices.

5. The principle of realism implies that the guaranteed scope of free medical care corresponds to the budget parameters.

6. The principle of regulation consists in state regulation of tariffs for medical services, prices for medicines and medical devices provided in provision of the guaranteed scope of free medical care.

## **Article 198. The goals of providing medical care within the guaranteed scope of free medical care**

The goals of providing medical care within the guaranteed scope 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) formation of the patient's skills to control their own health;
- 6) medical care for incurable patients in the terminal (final) stage of the disease.

## **Article 199. Minimum social standards in the field of healthcare**

The guaranteed scope of free medical care, ensuring the availability of healthcare services to the population shall be the minimum social standards in the field of healthcare in accordance with the Law of the Republic of Kazakhstan “On minimum social standards and their guarantees”.

## **Article 200. Medical care in compulsory social health insurance system**

1. The system of compulsory social health insurance provides:
  - 1) specialized medical care on an outpatient basis, including:

preventive medical examinations in the manner and with the periodic established by the authorized authority, except for preventive examinations within the guaranteed scope of free medical care;

reception and consultation by specialized specialists of patients in the direction of doctors of primary health care;

dynamic observation by specialized specialists of persons with chronic diseases in the manner and with the periodic established by the authorized authority;

provision of emergency and planned dental care to certain categories of the population according to the list determined by the authorized authority;

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

procedures and manipulations according to the list determined by the authorized authority ;

2) specialized, including high-tech, medical care in hospital-substituting conditions ( except for cases of treatment of diseases within the guaranteed scope of free medical care);

3) specialized, including high-tech, medical care in stationary conditions in a planned form (except for cases of treatment of diseases within the guaranteed scope of free medical care);

4) specialized inpatient care in an emergency form, including the conduct of medical and diagnostic measures in admission department of a round-the-clock hospital until a diagnosis shall be established that does not require treatment in a round-the-clock hospital (except for cases of treatment of diseases within the guaranteed scope of free medical care);

5) medical rehabilitation according to the list of diseases determined by the authorized authority;

6) postmortem diagnostics;

7) preparation of a posthumous donor for removal of organs (part of organ) and (or) tissues (part of tissue), removal, conservation, procurement, storage, transportation of organs ( part of organ) and (or) tissues (part of tissue) for the purpose of organ transplantation (parts of organ) and (or) tissues (parts of tissue).

2. Provision of medicines, medical devices, specialized medicinal products, immunobiological preparations in provision of medical care in the system of compulsory social health insurance shall be carried out in provision of:

1) specialized, including high-tech, medical care in inpatient and inpatient-substituting conditions in accordance with the medicinal forms of healthcare organizations;

2) primary health care and specialized medical care on an outpatient basis in accordance with the list of medicines, medical devices approved by the authorized authority for certain categories of citizens with certain diseases (conditions).

3. When providing medical care in the system of compulsory social health insurance, healthcare subjects use medicines, medical products and immunobiological drugs registered in the Republic of Kazakhstan, included in the Kazakhstan national drug formulary.

#### **Article 201. Medical care within voluntary health insurance**

Voluntary medical insurance shall be a type of personal insurance that allows you to receive medical services included in the guaranteed scope of free medical care and (or) the scope of medical care in compulsory social health insurance system, as well as additional programs, the costs of which shall be compensated by the insurance organization.

The voluntary health insurance program includes a list of:

medical services under a voluntary insurance contract, which shall be paid by the insured, indicating the total insured amount or separate insurance amounts for each type of medical services provided;

health care organizations where the policyholder (insured) receives medical services.

The list of medical services shall be established by the insurance organization in agreement with the policyholder (insured).

#### **Article 201-1. Medical care within the framework of imputed medical insurance**

1. Imputed medical insurance is a type of medical insurance for foreigners temporarily staying in the Republic of Kazakhstan, in accordance with the Law of the Republic of Kazakhstan "On population migration" and international treaties ratified by the Republic of Kazakhstan, allowing to receive medical services on the terms defined by the standard imputed medical insurance contract approved by the authorized body in coordination with the authorized body for regulation, control and supervision of the financial market and financial organizations.

2. The object of imputed medical insurance is the property interest of the insured person associated with the need to receive medical services as a result of the occurrence of an insured event determined by the standard contract of imputed medical insurance.

3. The insured risk is the probability of deterioration of the health of the insured person, resulting in the need to apply to medical organizations.

4. An insured event in the case of imputed medical insurance is the deterioration of the health of the insured person and the associated receipt of medical care in a medical organization:

1) primary health care;

2) specialized medical care in inpatient conditions in an emergency form.

The minimum list of medical care in case of imputed medical insurance is determined by the authorized body.

5. The amount of the insurance sum under the imputed medical insurance contract is determined by the terms of the agreement of the parties and must be at least the amount



determined in monthly calculation indices established by the law on the republican budget for the relevant financial year, in order to provide:

- 1) primary health care - at least fifty monthly calculation indices;
- 2) specialized medical care in inpatient conditions – at least one hundred monthly calculation indices.

6. Other conditions of imputed medical insurance are determined and established by the standard contract of imputed medical insurance.

**Footnote. Chapter 23 is supplemented with Article 201-1 in accordance with the Law of the Republic of Kazakhstan dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication).**

## **Article 202. Medical care provided through the provision of paid services and other sources**

1. Medical care provided on a paid basis (paid medical services) shall be provided by health care subjects in accordance with standards on a contractual basis.

2. The sources of formation of paid medical services shall be citizens' own funds, voluntary medical insurance funds, employers' funds and other sources not prohibited by the legislation of the Republic of Kazakhstan.

3. Paid medical services are provided to persons, including those held in pre-trial detention centers and institutions of the penal (penitentiary) system, in:

1) provision of medical care at their initiative, including without sending specialists of the primary and secondary levels;

2) provision of medical care in excess of the guaranteed scope of free medical care and (or) in the system of compulsory social health insurance;

3) treatment with medicinal products not included in the medicinal form of the healthcare organization;

4) conducting medical research that is not included in the list of guaranteed scope of free medical care and (or) the list of medical care in the compulsory social health insurance system, and (or) without medical indications;

5) rehabilitation treatment and medical rehabilitation provided in sanatorium organizations in excess of the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance, with the exception of persons held in pre-trial detention centers and institutions of the penal (penitentiary) system;

6) medical genetic research without medical indications;

7) medical examination not provided by the guaranteed scope of free medical care and in excess of the scope of compulsory social health insurance;

8) provision of medical care under a contract, including voluntary medical insurance;

9) provision of medical care to foreigners and stateless persons, except for the cases provided by Paragraphs 1 and 2 of Article 83 of this Code.

4. Paid non-medical services to persons shall be provided with additional services (additional household and service services, including stay in superior wards; additional care not due to medical indications; additional food; equipping wards and offices with additional types of non-medical equipment: telephone, TV, office equipment, refrigerator; transport and other services).

5. The types of paid services and the price list for them shall be brought to the attention of the population through visual information, including on Internet resources, by healthcare entities.

6. When providing paid services, healthcare entities maintain primary accounting and reporting documentation in medical healthcare information systems in the forms approved by the authorized authority.

7. The healthcare organization shall be responsible for the timely and high-quality provision of paid medical services to persons from the moment they apply in the manner established by the legislation of the Republic of Kazakhstan.

8. The procedure for provision of paid services by healthcare subjects shall be determined by the authorized authority in accordance with this Code and the laws of the Republic of Kazakhstan.

9. It shall be prohibited to provide, on a paid basis, medical care provided within the guaranteed scope of free medical care and (or) in the system of compulsory social health insurance.

**Footnote. Article 202 as amended by the law of the Republic of Kazakhstan dated 30.12.2021 № 95-VII (shall be enforced from 01.07.2022).**

## **Chapter 24. DONATION AND TRANSPLANTATION**

### **Item 1. Blood donation of and its components**

#### **Article 203. Donation, collection of blood, its components and production of blood products**

1. Blood donation and its components shall be the voluntary participation of donors in protecting the health of citizens through the implementation of the donated function.

2. Attraction of donors for implementation of the donor function shall be carried out free of charge or on a reimbursable basis.

Attraction of donors on a reimbursable basis shall be carried out in the absence of donors performing a donor function on a gratuitous basis.

3. The process of collecting blood and its components includes donation:

- 1) blood, which is the process of taking donated blood;
- 2) blood components, which is the process of taking individual blood components (plasma, cells).

4. In the process of collecting and processing blood, you get:

1) blood components, which are constituents of blood, secreted in the form of cells and cell-free media;

2) blood products, which are medicines produced during the processing of donated blood.

**Article 204. Healthcare organizations and other organizations carrying out activities in the field of donation, preparation of blood, its components and production of blood products**

1. Preparation, processing, storage and sale of blood, its components from allogeneic donors shall be carried out by state healthcare organizations that have an appropriate license.

2. The production of blood products shall be carried out by organizations that have the appropriate license.

3. Healthcare organizations and other organizations carrying out activities in the field of donation, preparation of blood, its components and preparations shall be responsible for their quality, and also sell blood and its components for the following purposes:

1) clinical use;

2) production of blood products;

3) use for the manufacture of reagents and (or) consumables for medical devices for diagnostics outside a living organism (in vitro) (including from blood components unsuitable for clinical use).

4. In the event of a state of emergency or martial law on the territory of the Republic of Kazakhstan, the organization of donation shall be carried out in accordance with the legislation of the Republic of Kazakhstan.

**Article 205. Ensuring the safety and quality of donated blood, its components and preparations**

1. The safety of donated blood, its components and preparations shall be ensured by compliance with the established requirements for medical examination of donors, safety and quality in the production of blood products for medical use, approved by the authorized authority.

The assessment of the quality of laboratory tests carried out in organizations operating in the field of blood services shall be carried out by the republican reference laboratory of the blood service.

2. It shall be prohibited to use and sell donated blood, its components, preparations without appropriate labeling.

3. Healthcare organizations and medical workers performing transfusion of donated blood, its components and preparations shall be obliged to ensure compliance with the relevant requirements for their safe use, as well as the procedure for provision of transfusion care.

**Article 206. Rights and obligations of donors of blood and its components**

1. A donor has the right to be an individual who has reached the age of eighteen, has passed an appropriate medical examination and has no contraindications, who has expressed a voluntary desire to donate blood and its components for medical purposes.

2. The donor has the right:

- 1) donate blood and its components free of charge;
- 2) donate blood and its components for a fee;
- 3) get acquainted with the results of medical examination;
- 4) be encouraged in accordance with this Code.

3. The donor shall be obliged to provide information known to him about all existing and previously transferred diseases, as well as about the use of narcotic drugs, psychotropic substances, their analogues and precursors.

#### **Article 207. Donor medical examination**

1. Before the donation of blood and its components, the donor undergoes a compulsory medical examination within the guaranteed scope of free medical care in the manner determined by the authorized authority.

2. Certificates of health status for implementation of the donor function shall be issued in the state healthcare organizations free of charge.

3. Medical examination of donors of blood and its components shall be carried out within the guaranteed scope of free medical care.

#### **Article 208. Guarantees provided to the donor, the rights and obligations of employers and organizations for development of blood donation and its components**

1. An employee during a medical examination and blood donation and (or) its components on working days shall be released from work with the preservation of the average wage.

2. A donor who donated blood and (or) its components on a gratuitous basis shall be provided with an additional day of rest with the preservation of the average wage, which can be added to the annual labor leave. These guarantees shall be valid for one year from the date of donation.

In case of a failed donation of blood and its components, an additional day of rest shall not be provided.

3. In the event that, by agreement with the employer, an employee who is a donor, on the days of donating blood and (or) its components, has begun work, he is given, at his request, another day of rest with the preservation of his average wage, or this day can be added to the annual labor leave.

4. It shall not be allowed to involve an employee who is a donor on the days of donating blood and (or) its components to work at night, overtime work, heavy work, work with harmful and (or) dangerous working conditions.

5. Military personnel, employees of law enforcement and special state authorities, as well as students (pupils) who are donors, on the days of donating blood and (or) its components shall be exempt from duty, watch and other forms of service and from the educational process

6. Donors shall be encouraged in accordance with the legislation of the Republic of Kazakhstan.

7. A donor who donated blood and (or) its components on a gratuitous basis, to replenish the volume of his blood and energy expenditures of the body after donating blood and (or) its components at his choice, receives free food or its monetary equivalent in the amount established by the authorized authority.

In case of failed donation of blood and (or) its components, free food or its monetary equivalent to replenish the volume of one's own blood and energy expenditure of the authority after donating blood and (or) its components shall not be issued.

8. A donor of blood, its components, who donates blood and its components on a reimbursable basis, a healthcare organization that carries out activities in the field of procurement of blood and its components shall be paid.

9. The procedure, criteria and amount of payments to donors who donate blood and its components on a reimbursable basis shall be established by the authorized authority.

10. Employers and heads of organizations, in order to create conditions for development of donation, shall be obliged to:

1) provide assistance to local government healthcare authorities, state healthcare organizations in attracting citizens of the Republic of Kazakhstan to the ranks of donors;

2) provide the necessary premises free of charge and create conditions for taking blood and its components;

3) unimpeded to release the employee who is the donor from work on the day of examination and donation of blood and its components;

4) provide the employee who is a donor with the guarantees established by this Code.

11. Employers and heads of organizations have the right to further encourage donors.

## **Item 2. Transplantation of organs (part of organ) and (or) tissues (part of tissue)**

### **Article 209. Transplantation of organs (part of organ) and (or) tissues (part of tissue) and conditions for their removal**

1. Transplantation of organs (part of organ) and (or) tissues (part of tissue) shall be carried out from a donor to a recipient and consists of the following stages: removal, conservation, storage, transportation and transplantation of organs (part of an organ) and (or) tissues (part of tissue).

2. Removal, conservation, storage, transportation and transplantation of organs (part of organ) and (or) tissues (part of tissue) shall be carried out in state medical organizations, one

hundred percent of the voting shares (stakes in the authorized capital) of which belong to the state, as well as in the medical organizations "Nazarbayev University" in the presence of a license to carry out medical activities for the provision of organ (part of an organ) and (or) tissue (part of tissue) transplantation services in accordance with profile of medical activity.

3. Removal of organs (part of an organ) and (or) tissues (part of tissue) for further transplantation to a person (potential recipient) shall be performed from a living person (intravital donor) or deceased (posthumous donor).

4. When transplanting organs (part of organ) and (or) tissues (part of tissue), it shall be prohibited:

1) forced removal of organs (part of an organ) and (or) tissues (part of tissue) from a person;

2) forcing a person to provide his organ (part of organ) and (or) tissues (part of tissue);

3) buying and selling organs (parts of an organ) and (or) tissues (parts of tissue) of a person;

4) removal of organs (part of organ) and (or) tissues (part of tissue) from an intravital donor or a posthumous donor who is a minor or incapacitated person;

5) removal of organs (part of organ) and (or) tissues (part of tissue) from a posthumous donor for transplantation to foreigners and stateless persons;

6) removal of organs (part of organ) and (or) tissues (part of tissue) from persons who, for health reasons, age or other reasons, could not provide data about their identity and whose identity was not established at the time of ascertaining death.

5. Removal of organs (part of organ) and (or) tissues (part of tissue) from an infected living donor or posthumous donor for transplantation to a recipient shall be prohibited.

The list of infectious diseases in which transplantation of organs (part of organ) and (or) tissues (part of tissue) from a donor is permitted shall be approved by the authorized authority

6. To ensure the transplantation of organs (part of organ) and (or) tissues (part of tissue), a register shall be formed:

1) potential recipients of organs (part of organ) and (or) tissues (part of tissue);

2) recipients of organs (part of organ) and (or) tissues (part of tissue);

3) donors of organs (parts of organ) and (or) tissues (part of tissue);

4) citizens who have expressed the right to posthumous donation of organs (part of organ) and (or) tissues (part of tissue).

7. The procedure for formation and maintenance of the register shall be determined by the authorized authority.

8. Registration of the will of a citizen of the Republic of Kazakhstan on consent or refusal to remove organs (part of organ) and (or) tissues (part of tissue) from him after death for the purpose of transplantation in the register of citizens who have expressed the right to posthumous donation of organs (part of organ) and (or) tissue (part of tissue), can be

produced by direct contact with a medical organization providing primary health care, or on the web portal of "electronic government".

Access to the register of citizens who have expressed the right to posthumous donation of organs (part of organ) and (or) tissues (parts of tissue) shall be possible only for authorized persons of the Coordination Center for Transplantation in the manner determined by the authorized authority.

**Footnote. Article 209 as amended by the Law of the Republic of Kazakhstan dated 31.03.2021 № 24-VII (shall be enforced upon expiration of ten calendar days after the date of its first official publication ).**

**Article 210. The procedure for transplantation of organs (part of organ) and (or) tissues (part of tissue) from an intravital donor**

1. An intravital donor of an organ (part of organ) and (or) tissues (part of tissue) may be a person aged eighteen and older, capable, who is in genetic connection with the recipient and (or) has tissue compatibility with him, who has expressed a written notarially certified consent to the removal of an organ (part of organ) and (or) tissues (part of tissue) for further transplantation.

2. For transplantation, only one of the paired organs, a part of organ or tissue, the removal of which will not entail an irreversible health disorder, may be removed from a living donor.

3. An intravital donor must undergo a comprehensive medical examination in the manner prescribed by the authorized authority.

4. To establish a genetic link between a potential recipient and an intravital donor, an Ethics Commission shall be created. The composition and position of the Ethics Commission shall be approved by the authorized authority.

**Article 211. Coordination and support of organ transplantation (part of organ) and (or) tissues (part of tissue)**

1. Coordination Center for Transplantation - a healthcare organization dealing with the coordination and support of organ transplantation (part of organ) and (or) tissues (part of tissue), the regulation of which shall be approved by the authorized authority.

2. Determination of the immunological compatibility of tissues during transplantation shall be carried out in tissue typing laboratories (HLA-laboratories), functioning as a structural unit under state medical organizations that carry out activities in the field of donation, preparation of blood, its components and preparations.

The rules for determining the immunological compatibility of tissues during transplantation of organs (part of organ) and (or) tissues (parts of tissue) and the regulation on the activities of the HLA laboratory shall be developed and approved by the authorized authority.

Determination of the immunological compatibility of tissues during transplantation shall be carried out on the basis of a referral for research from an organization licensed to carry out medical activities for provision of services for organ transplantation (part of organ) and (or) tissues (part of tissue).

3. The activity of tissue banks shall be aimed at the formation of stocks of biological materials and their provision to healthcare organizations carrying out transplantation.

4. The procedure for carrying out the activities of the tissue bank shall be determined by the authorized authority.

**Article 212. The procedure for transplantation of organs (part of organ) and (or) tissues (part of tissue) from a posthumous donor**

1. A posthumous donor may be a person aged eighteen and older, who has been diagnosed with irreversible death of the brain, whose organs (parts of organ) and (or) tissue (parts of tissue) can be used for transplantation to a recipient.

2. The procedure for giving a person's lifetime expression of will to posthumous donation of organs (parts of organ) and (or) tissues (parts of tissue) and notifying a spouse or one of close relatives about this shall be determined by the authorized authority.

3. Removal of organs (part of organ) and (or) tissues (part of tissue) from a posthumous donor for transplantation shall not be allowed if the medical organization at the time of removal being informed that the person concerned during life or after his death other persons specified in part two of this Paragraph, declared their disagreement with the removal of his organs (part of organ) and (or) tissues (part of tissue).

In the absence of a person's lifetime expression of will, the spouse has the right to declare in writing his disagreement (consent) to removal of his organs (part of organ) and (or) tissues (parts of tissue) for transplantation, and in his (her) absence, one of close relatives.

4. Removal and conservation of visual organs from corpses for the purpose of transplantation shall be carried out in organizations carrying out the activities of pathological anatomy and forensic medical examination, in the manner determined by the authorized authority in agreement with the authorized authority in the field of forensic expertise.

5. The procedure and conditions for removal, conservation, storage, transportation and transplantation of organs (parts of organ) and (or) tissues (parts of tissue) shall be determined by the authorized authority.

6. Participation of persons carrying out the removal of organs (part of organ) and (or) tissues (part of tissue) for subsequent transplantation in the statement of irreversible death of the brain shall be prohibited.

7. This Article shall not apply to organs (parts of organ) and (or) tissues (parts of tissue) related to the process of human reproduction, including reproductive tissues (germ cells), as well as blood, its components, hematopoietic stem cells, cells of the human body and (or) animal for use in biomedical purposes.



**Article 213. The rights of donor and recipient of organs (part of organ) and (or) tissues (part of tissue)**

1. The donor has the right:

1) demand full information from healthcare organizations about possible complications for his health in connection with the forthcoming intervention to remove organs (part of organ ) and (or) tissues (part of tissue);

2) undergo a medical examination in order to be included in the register of organ donors ( organ parts) and (or) tissues (tissue parts) within the guaranteed scope of free medical care and (or) in the system of compulsory social health insurance;

3) receive treatment, including medication, in health care organizations in connection with the intervention performed to remove organs (part of organ) and (or) tissues (part of tissue) within the guaranteed scope of free medical care and (or) in the system of compulsory social medical insurance;

4) refuse before the start of the surgical intervention for transplantation.

2. The recipient has the right:

1) demand full information from the healthcare organization about possible complications for his health in connection with the upcoming intervention for transplantation of organs (part of organ) and (or) tissues (part of tissue);

2) undergo a medical examination to be included in the register of potential recipients of organs (parts of organ) and (or) tissues (parts of tissue) within the guaranteed scope of free medical care and (or) in the system of compulsory social health insurance.

3) to receive treatment, including medication, in a health care organization in connection with the intervention for removal and transplantation of donor organs (part of organ) and (or) tissues (part of tissue) within the guaranteed scope of free medical care;

4) refuse before the start of the surgical intervention for transplantation.

3. Medical and other employees of health care organizations shall be prohibited from disclosing information about the donor and (or) recipient.

**Article 214. Obligations of employers and heads of organizations to create conditions for development of organ donation (part of organ) and (or) tissues (part of tissue)**

1. Employers and heads of organizations, in order to create conditions that ensure the development of organ donation (part of organ) and (or) tissues (part of tissue), shall be obliged to free from work an employee who is a donor of organs (part of organ) and (or) tissues (part of tissue).

2. An employee who is a donor of organs (parts of organ) and (or) tissues (parts of tissue) shall be provided with a sheet of temporary disability in accordance with the legislation of the Republic of Kazakhstan, taking into account the time for travel to a medical organization where organs (parts of organ) and (or) tissues (parts of tissue) for the purpose of

transplantation, and back to the place of residence while maintaining the average monthly wage.

3. Employers and leaders of organizations have the right to additionally encourage donors of organs (part of organ) and (or) tissue (part of tissue).

#### **Article 215. Register of donors of hematopoietic stem cells (bone marrow)**

1. Formation and maintenance of the register of donors of hematopoietic stem cells (bone marrow) in order to ensure the transplantation of hematopoietic stem cells shall be carried out in the manner determined by the authorized authority.

2. The procedure for searching and activating a donor of hematopoietic stem cells, including from international registries, and transporting hematopoietic stem cells to the recipient shall be determined by the authorized authority.

#### **Article 216. Transplantation of artificial organs (part of organ) and (or) tissues (part of tissue)**

1. Transplantation of artificial organs (part of organ) and (or) tissues (part of tissue) shall be carried out when:

- 1) organ failure;
- 2) the absence of donor organs (part of organ) and (or) tissues (part of tissue);
- 3) the absence of contraindications for transplantation of artificial organs and tissues.

2. The list of indications and contraindications for transplantation of artificial organs (parts of organ) and (or) tissues (parts of tissue) shall be developed and approved by the authorized authority.

3. Citizens of the Republic of Kazakhstan with artificial organs (parts of organ) and (or) tissues (parts of tissue), if necessary, shall be included in the register of potential recipients of organs (parts of organ) and (or) tissues (parts of tissue) in the manner determined by the authorized authority.

#### **Item 3. Import, export of organs (parts of organ) and (or) tissues (parts of tissue) of a person, hematopoietic stem cells (bone marrow), blood and its components, samples of cells, biological fluids and human secretions**

#### **Article 217. Grounds for import, export of organs (parts of organ) and (or) tissues (parts of tissue) of a person, hematopoietic stem cells (bone marrow), donor lymphocytes, germ cells, embryos**

1. The import of organs (part of organ) and (or) tissues (part of tissue) of a person, hematopoietic stem cells (bone marrow), donor lymphocytes into the territory of the Republic of Kazakhstan shall be carried out when:

- 1) the need for transplantation in healthcare organizations;
- 2) the need for diagnostic tests on the territory of the Republic of Kazakhstan;
- 3) conducting joint scientific research.

2. Removal of organs (part of organ) and (or) tissues (part of tissue) of a person, hematopoietic stem cells (bone marrow), donor lymphocytes from the territory of the Republic of Kazakhstan shall be carried out:

1) if it is necessary to provide medical care to a citizen of the Republic of Kazakhstan who is outside the Republic of Kazakhstan;

2) if necessary, diagnostic tests;

3) when conducting joint scientific research;

4) in cases provided by international treaties ratified by the Republic of Kazakhstan;

5) if necessary, transplantation of hematopoietic stem cells (bone marrow), donor lymphocytes from a donor living in the Republic of Kazakhstan, to a recipient living abroad and awaiting transplantation.

3. A license to import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of organs (part of organ) and (or) tissues (part of tissue) of a person in the cases provided by Subparagraph 1) Paragraph 1 and Subparagraphs 1) and 4) of Paragraph 2 of this Article, issued by the authorized authority at the request of healthcare organizations operating in the specialty "transplantology", "hematology" in accordance with a license for medical activities, in cases of placement of organs (part of organ) and (or) tissues (part of tissue) of a person under customs procedures for export or release for domestic consumption.

4. Conclusion (permitting document) for import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of organs (parts of organ) and (or) tissues (parts of tissue) of a person premises under the customs procedures for processing in the customs territory, processing outside the customs territory, processing for domestic consumption and in the case of placement under customs procedures for re-export and re-import in order to complete the customs procedures for processing in the customs territory, processing outside the customs territory and processing for domestic consumption shall be issued by the authorized authority.

5. Import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of hematopoietic stem cells (bone marrow), donor lymphocytes in the event of their movement for the purpose of unrelated transplantation shall be carried out on the basis of the conclusion (permitting document) issued by the authorized authority.

6. Import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of germ cells and embryos shall be carried out on the basis of an opinion (permit) issued by the authorized authority in the following cases:

1) the need for in vitro fertilization in health care organizations of the Republic of Kazakhstan;

2) the need for diagnostic tests;

3) conducting joint scientific research;

4) if necessary, in vitro fertilization to a citizen of the Republic of Kazakhstan who is outside the Republic of Kazakhstan;

5) if necessary, in vitro fertilization to close relatives and spouses of citizens of the Republic of Kazakhstan located outside the Republic of Kazakhstan;

6) if necessary, in vitro fertilization of a donor living in the territory of the Republic of Kazakhstan, a recipient living abroad;

7) provided by international treaties ratified by the Republic of Kazakhstan.

7. Import and export of organs (parts of organ) and (or) tissues (parts of tissue) of a person, germ cells and embryos, hematopoietic stem cells (bone marrow), donor lymphocytes by individuals shall not be allowed.

8. The procedure for biological safety research, preservation and transportation of tissues (parts of tissues) of a person and (or) organs (parts of organ) intended for import and export shall be determined by the authorized authority.

#### **Article 218. Grounds for import, export of blood and its components, samples of human biological materials**

1. The import of blood and its components, samples of human biological materials into the territory of the Republic of Kazakhstan shall be carried out at:

1) the need to provide medical care on the territory of the Republic of Kazakhstan;

2) the need for diagnostic tests on the territory of the Republic of Kazakhstan;

3) conducting joint scientific research;

4) the need to conduct laboratory studies using the HLA system to confirm the tissue compatibility of a donor living abroad and a recipient living in the Republic of Kazakhstan, as well as to carry out immunostimulation of the recipient as part of hematopoietic stem cell transplantation.

2. Export of blood and its components, samples of human biological materials from the territory of the Republic of Kazakhstan shall be carried out:

1) if it is necessary to provide medical care to a citizen of the Republic of Kazakhstan who is outside the Republic of Kazakhstan, as well as recipients living abroad;

2) if it is necessary to provide medical assistance to close relatives and spouses of citizens of the Republic of Kazakhstan located outside the Republic of Kazakhstan;

3) if necessary, diagnostic tests;

4) when conducting joint scientific research;

5) in cases provided by international treaties ratified by the Republic of Kazakhstan;

6) when sending blood components harvested in state healthcare organizations operating in the field of blood service of the Republic of Kazakhstan, abroad for production of plasma blood products at factories of a foreign manufacturer in order to provide the population of the Republic of Kazakhstan with blood products (contract fractionation);

7) if it is necessary to conduct laboratory studies using the HLA system in order to confirm the tissue compatibility of a donor living in the Republic of Kazakhstan and a recipient living abroad, as well as immunostimulation of the recipient within the hematopoietic stem cell transplantation;

8) when sending blood components and (or) samples of human biological materials abroad as raw materials used in the manufacture of reagents and (or) consumables for medical devices for diagnostics outside of a living organism (in vitro).

3. In addition to the cases provided by Paragraphs 1 and 2 of this Article, the import and export of blood and its components, samples of human biological materials may be carried out in the manner of exchange, carried out only in the absence of blood and its components with the necessary biological properties.

4. A license to import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of blood and its components in the cases provided by Subparagraph 1) of Paragraph 1 and Subparagraphs 1), 2) and 5 ) of Paragraph 2 of this Article, shall be issued by the authorized authority at the request of healthcare organizations carrying out activities in the specialty of "blood banking" in accordance with the license for medical activities, and in the cases provided by Subparagraph 6) of Paragraph 2 of this Article , issued by the authorized authority at the request of a legal entity in cases of placing blood and its components under customs procedures for export or release for domestic consumption.

5. Conclusion (permitting document) for import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of blood and its components in cases of their placement under the customs procedures of processing in the customs territory, processing outside the customs territory or processing for domestic consumption and in the case of placement under the customs procedures of re-export and re-import in order to complete the customs procedures for processing in the customs territory, processing outside the customs territory and processing for domestic consumption shall be issued by the authorized authority.

6. Import into the territory of the Republic of Kazakhstan and export from the territory of the Republic of Kazakhstan samples of human biological materials used for diagnostic and scientific purposes, intended for external quality control of research, including for reference research, or obtained in the course of biomedical research and (or) clinical trials shall be carried out on the basis of an opinion (permit) issued by the authorized authority.

7. Import and export of blood and its components, samples of human biological materials by individuals shall not be allowed, except for the cases provided by Subparagraph 4) of Paragraph 1 and Subparagraph 7) of Paragraph 2 of this Article.

**Article 219. The procedure for import, export of organs (parts of organ) and (or) tissues (parts of tissue) of a person, blood and its components**

1. Import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of organs (parts of organ) and (or) tissues (parts of tissue) of a person, blood and its components by healthcare organizations specified in Paragraph 3 of Article 217 and Paragraph 4 of Article 218 of this Code, shall be carried out on the basis of a license issued in the manner prescribed by the Law of the Republic of Kazakhstan "On Permits and Notifications", or an opinion (permitting document).

2. The authorized authority, within three working days, makes a decision on issue or refusal to issue a license for import, export of human tissues (part of tissues), blood and its components, and for import, export of human organs (part of an organ) - within one work day

3. Decision to issue or refuse to issue an opinion (permit) for import, export of organs (part of organ) and (or) tissues (part of tissue) of a person, blood and its components in cases of placement of organs and tissues of a person, blood and its components under the customs procedures for processing in the customs territory, processing outside the customs territory or processing for domestic consumption and in the case of placement under the customs procedures of re-export and re-import in order to complete the customs procedures for processing in the customs territory, processing outside the customs territory and processing for domestic use, the authorized authority shall accept within three working days.

**SECTION 4. EDUCATIONAL AND SCIENTIFIC ACTIVITIES IN THE FIELD OF HEALTHCARE Chapter 25. EDUCATIONAL ACTIVITY IN THE FIELD OF HEALTHCARE**

**Article 220. Subjects of educational activity in the field of healthcare and conditions for its implementation**

1. Educational activity in the field of healthcare shall be carried out in organizations of medical and pharmaceutical education, scientific organizations in the field of healthcare and other educational organizations that implement educational programs in the field of healthcare

2. Education in the field of healthcare includes:

- 1) medical education programs implemented in medical specialties;
- 2) programs of pharmaceutical education implemented in pharmaceutical specialties;
- 3) training programs for public health professionals and other healthcare professionals.

Organizations of higher and (or) postgraduate education that implement educational programs in the field of healthcare, created in the organizational and legal form of a non-profit joint-stock company, have autonomy in all areas of activity in accordance with the legislation of the Republic of Kazakhstan and shall be guided by the principles of freedom of teaching, research and creativity.

3. Mandatory conditions for implementation of educational programs in the field of healthcare in medical specialties shall be:

1) the presence of a simulation room (center) in the structure of the organization of education in the field of healthcare;

2) in preparation of doctors - the implementation in the organization of higher and (or) postgraduate education programs of integrated and postgraduate medical education (residency , doctoral studies);

3) attracting mentors from among qualified medical workers during the training of students at clinical bases;

4) formation in organizations of higher and (or) postgraduate education of university hospitals and (or) integrated academic medical centers operating on the basis of agreements with scientific organizations in the field of healthcare and healthcare organizations.

4. The scientific and practical bases of educational organizations in the field of healthcare shall be clinical bases, clinics of educational organizations in the field of healthcare, university hospitals, residency bases.

The regulations on clinical base, the clinic of the organization of education in the field of healthcare, the university hospital, the residency base, the integrated academic medical center and the requirements for them shall be developed and approved by the authorized authority.

Clinical bases, clinics of educational organizations in the field of healthcare, university hospitals, residency bases shall be subject to the accreditation procedure established by Paragraph 2 of Article 25 of this Code in order to recognize the compliance of the provided medical services with the established requirements and standards in the field of healthcare, as well as the requirements for clinical bases, clinics of educational organizations in the field of healthcare, university hospitals, residency bases.

5. Scientific organizations and educational organizations in the field of healthcare within the achieving strategic goals of sustainable development have the right to conclude agreements with foreign higher educational institutions and medical organizations in the field of educational, scientific, clinical activities.

The procedure for implementing strategic partnership in the field of medical education and science shall be determined by the authorized authority.

6. Associations of educational organizations in the field of healthcare, accredited by the authorized authority for coordination of actions to ensure the quality of educational activity in the field of healthcare, have the right:

1) develop the state compulsory standards for levels of education in the field of healthcare , model curricula and programs, guidelines and recommendations aimed at ensuring the quality of educational activities in the field of healthcare;

2) represent the interests of subjects of educational activities in the field of healthcare in advisory and expert bodies, working groups formed by the authorized authority.

### **Article 221. Specifics of educational activity in the field of healthcare**

1. The objectives of educational activity in the field of healthcare shall be to train professional scientific, pedagogical, medical and pharmaceutical personnel, public health specialists and other specialists for healthcare system and improve their qualifications.

2. State compulsory standards for levels of education in the field of healthcare shall be approved by the authorized authority and determine the set of general requirements for the scope of the academic load (number of credits) and competence of the graduate.

Organizations of higher and (or) postgraduate education independently develop educational programs in accordance with the requirements of state compulsory standards, as well as taking into account the requirements for the level of qualifications established by professional standards in the field of healthcare.

The list of educational programs shall be contained in the register of educational programs by levels of education in the field of healthcare. The maintenance of the register and the procedure for inclusion in the register of educational programs by levels of education in the field of healthcare shall be carried out in the manner determined by the authorized authority.

3. Training of medical personnel shall be carried out according to the programs of continuous integrated medical education. Upon completion of training under the programs of continuous integrated medical education, the graduate who has passed the final certification shall be awarded the degree "Master of Medicine". Upon completion of training in the internship, the graduate who has passed the assessment of professional preparedness shall be awarded the qualification "doctor".

An internship is a form of training for students in clinical specialties within the continuous integrated medical education, in which they undergo general medical practice under the supervision of a mentor, as a result of which they acquire knowledge in the field of general medicine and clinical experience.

4. For persons who have mastered educational programs of technical and vocational, post-secondary, higher, postgraduate and additional education, the basis for carrying out professional activities in the field of healthcare shall be a state-recognized education certificate, and for medical specialties also a certificate of a healthcare specialist, except for doctors-residents during their residency studies.

5. Postgraduate medical and pharmaceutical education includes residency, master's and doctoral studies.



Persons with a Master's degree shall be eligible to enroll in a non-clinical doctoral program.

Persons who have completed their residency training shall be eligible to enroll in a doctoral program of clinical profile.

In organizations of higher and (or) postgraduate medical education, programs of continuous postgraduate medical education may be implemented, including residency and doctoral programs of a clinical profile.

6. The acquisition of additional knowledge and skills by healthcare professionals shall be carried out through additional and non-formal education.

Additional education shall be carried out in educational and scientific organizations that implement educational programs of additional education and have passed institutional accreditation in accreditation authorities entered in the register of recognized accreditation authorities.

Additional education on disinfection, disinsection, deratization in the field of healthcare is carried out by educational and scientific organizations, professional self-regulating organizations implementing educational programs of additional education and having passed institutional accreditation in accreditation bodies included in the register of recognized accreditation bodies.

Additional education in medical specialties and non-formal education of medical workers shall be carried out by organizations of higher and (or) postgraduate education, national and scientific centers, research institutes, higher medical colleges on the basis of accredited clinical bases, clinics of educational organizations in the field of healthcare, university hospitals.

The procedure for additional and non-formal education of healthcare professionals, qualification requirements for organizations that implement educational programs of additional and non-formal education in the field of healthcare, as well as the rules for recognizing learning outcomes obtained by healthcare professionals through additional and non-formal education, shall be determined by the authorized authority.

7. Educational organizations in the field of healthcare determine the procedure for attestation of scientific and pedagogical personnel and the requirements for them. Certification of scientific and pedagogical personnel should be carried out at least once every five years. Educational organizations in the field of healthcare provide regular improvement of the pedagogical, research and professional competence of scientific and pedagogical personnel.

Scientific and pedagogical personnel of organizations of higher and (or) postgraduate medical education with one hundred percent participation of the state have the right to advanced training at the expense of budgetary funds.

Footnote. Article 221 as amended by the Law of the Republic of Kazakhstan dated 21.05.2022 № 123-VII (shall be enforced six months after the date of its first official publication).

## **Article 222. Residency**

1. The implementation of residency programs shall be carried out by organizations of higher and (or) postgraduate education in accredited clinics of educational organizations in the field of healthcare, university hospitals, as well as national and (or) scientific centers, research institutes accredited as residency bases. Residency programs shall be implemented in medical specialties, the list of which shall be approved by the authorized authority.

2. The organization of higher and (or) postgraduate education, national and (or) scientific centers, research institutes independently develop educational residency programs in accordance with the requirements of the State Compulsory Education Standard of the Republic of Kazakhstan, as well as in accordance with the requirements for qualification levels established professional standards in the field of healthcare.

The list of educational residency programs shall be contained in the register of educational programs by levels of education in the field of healthcare.

3. A person studying in residency in order to change professional qualifications, masters the program in accordance with independently developed organizations of higher and (or) postgraduate education abbreviated educational programs based on the State Compulsory Education Standard of the Republic of Kazakhstan and requirements for the level of qualifications of graduates, taking into account the recognition of previously achieved learning outcomes of formal education.

4. Training in residency shall be carried out on the basis of integration of theory and clinical practice, with involvement of resident doctors in personal participation in provision of medical services and responsibility for patient care activities under the supervision of a mentor. The training process provides an increasing degree of independent responsibility of the resident physician as skills, knowledge and experience shall be acquired.

The rules for placing a state order, admission for education and training of medical personnel in residency shall be approved by the authorized authority.

5. The legal basis for training a resident doctor and attracting him to the provision of services shall be:

1) on the basis of residency of an organization of higher and (or) postgraduate education - a training agreement concluded between the organization of higher and (or) postgraduate education, the residency base and a resident doctor;

2) in the national and (or) scientific centers, research institutes accredited as residency bases - a training agreement concluded between the national and (or) scientific center, research institute and a resident doctor.

The form of a model agreement on training under the residency program shall be approved by the authorized authority.

Training in residency provides for provision of a workplace for a resident doctor with equal responsibility of the residency base, the organization of higher and (or) postgraduate education, as well as the national and (or) scientific center, research institute.

During the period of study, the resident doctor shall be subject to the labor regulations, safety and labor protection requirements of the residency base of the organization of higher and (or) postgraduate education, national and (or) scientific center, research institute.

6. Mastering a professional residency curriculum shall be a prerequisite for admission to independent clinical practice of citizens who graduated from the program of continuous integrated medical education and received the qualification "doctor".

### **Article 223. Assessment of trainees, medical graduates and healthcare professionals**

1. Assessment of knowledge and skills of students and professional preparedness of graduates of educational programs in the field of healthcare shall be based on:

1) requirements for the competencies of graduates of educational programs of the relevant specialty;

2) industry qualifications framework and professional standard.

2. Assessment of knowledge and skills of students in educational programs in the field of healthcare shall be carried out in accordance with the learning outcomes.

3. The assessment of professional preparedness of graduates of educational programs in the field of healthcare shall be carried out in accordance with the final results of training in the corresponding educational program.

The assessment of professional preparedness of graduates of educational programs in the field of healthcare shall be included in the structure of the final certification (state examination), final control. The positive results of the final certification (state exam), final control of graduates of educational programs in the field of healthcare give the right to receive a certificate of education and a certificate of a specialist in healthcare.

4. Assessment of professional preparedness of healthcare professionals shall be carried out in accordance with the requirements of the professional standard.

5. The assessment of knowledge and skills of students, the professional preparedness of graduates and healthcare professionals shall be carried out by an organization accredited by the authorized authority to assess the knowledge and skills of students and the professional preparedness of graduates of educational programs, healthcare professionals.

6. The rules for assessing the knowledge and skills of students, assessing the professional preparedness of graduates of educational programs in the field of healthcare, assessing the professional preparedness of specialists in the field of healthcare shall be determined by the authorized authority.

## **Article 224. Professional oath of a medical worker of the Republic of Kazakhstan**

Graduates of educational organizations implementing educational programs of technical and professional, post-secondary, higher and continuous integrated medical education, take the professional oath of a medical worker of the Republic of Kazakhstan with the following content:

“Accepting the high title of a medical worker, in front of my teachers and colleagues, I solemnly swear to honestly and faithfully serve the great cause of protecting human health. In my work I swear to be guided only by the interests of my patients, whose health is the highest value. I vow with equal diligence and patience to provide medical care to everyone who needs it, regardless of age, gender, nationality, religion, social status and citizenship. I swear to keep the secret of a medical worker, never to use it for personal gain. I vow to constantly improve my knowledge and skills, to be demanding of myself and my students, never refuse disinterested help and seek advice from colleagues myself, if the patient's interests require it. I swear to protect and enhance the noble traditions of Kazakhstan medicine, to keep gratitude and respect for those who taught me the art of medicine”.

## **Chapter 26. HEALTHCARE SCIENTIFIC ACTIVITY**

### **Article 225. Subjects of scientific activity**

1. The subjects of scientific activity in the field of health care shall be individuals and legal entities carrying out biomedical research.

Scientific organizations in the field of healthcare include legal entities engaged in scientific, scientific and technical and innovative activities, as well as conducting research and development work in the field of healthcare.

The status of the scientific center and research institute shall be assigned to a healthcare organization by the authorized authority. The authorized authority decides on preservation of the status of the scientific center and research institute for a healthcare organization based on the results of assessing the effectiveness of scientific, scientific, technical and innovative activities.

The procedure for assigning and revising the status of a scientific organization in the field of healthcare, as well as the procedure for assessing the effectiveness of scientific, scientific, technical and innovative activities shall be determined by the authorized authority in agreement with the authorized authority in the field of science.

2. Subjects of scientific activity in the field of healthcare conduct biomedical research in compliance with the standards and requirements for conducting biomedical research adopted at the international level and in the Republic of Kazakhstan, bioethical norms.

### **Article 226. Management of scientific activity**

1. The authorized authority coordinates and monitors the development of biomedical research.
2. The authorized authority organizes scientific and medical expertise:
  - 1) projects of programs of applied scientific research;
  - 2) results of completed scientific and medical programs;
  - 3) scientific works nominated for state awards of the Republic of Kazakhstan;
  - 4) scientific and medical developments planned for implementation in healthcare practice.The procedure for conducting scientific and medical expertise shall be determined by the authorized authority.

#### **Article 227. Biomedical Research**

1. Biomedical research can be carried out on living people and experimental (laboratory) animals (subjects of research), biological samples of living and dead people and animals, as well as on the basis of the use of clinical and epidemiological data and other medical information.

Biomedical research includes basic and applied biomedical research. Applied biomedical research includes biomedical experiments, preclinical (non-clinical) research, clinical research, and public health research.

2. The creation of human embryos for biomedical research and human cloning shall be prohibited.

3. Biomedical research of human embryos or human fetuses, during or after which the human embryo or human embryo shall be destroyed, shall be prohibited.

4. Clinical trials shall be carried out subject to the receipt of positive results of biomedical experiments, preclinical (nonclinical) studies.

5. Applied biomedical research can be carried out only if the following requirements are met:

1) biomedical research shall be aimed at obtaining new scientific data and their introduction into practical healthcare;

2) protection of the interests of the research subject and the confidentiality of his medical information shall be ensured;

3) consent of the research subject or his legal representative has been obtained to participate in the research or to use his biological samples and medical information, including for filling out the biobank for scientific purposes;

4) interventional clinical trials of medicines, medical devices shall be carried out with the permission of the authorized authority.

6. For the following categories of persons, biomedical research shall be conducted only when it cannot be performed on other persons and there is scientific reason to expect that participation in such biomedical research will bring them direct benefits, outweighing the risks and inconveniences associated with biomedical research:

- 1) minors;
- 2) pregnant women;
- 3) incapacitated;
- 4) students in cases where participation in biomedical research shall be related to their studies;
- 5) retirees in need of outside help;
- 6) servicemen and employees of law enforcement and special state authorities;
- 7) personnel of medical organizations where biomedical research shall be carried out;
- 8) persons held in institutions of the penal system.

Interventional clinical trials on the categories of persons specified in Subparagraphs 1), 2), 3), 4) and 5) of Paragraph 6 of this Article shall be carried out only to study the therapeutic effect.

Interventional clinical trials on the categories of persons specified in Subparagraphs 6), 7) and 8) of Paragraph 6 of this Article shall be prohibited.

7. Upon receipt of written consent to participate in biomedical research, a volunteer or patient, legal representative of a minor, guardian of an incapacitated person must be provided with information:

- 1) on medical technology, pharmacological or medicinal product, nature and duration of medical research;
- 2) on degree of safety, risks and expected effectiveness of medical technology, pharmacological or medicinal product;
- 3) on actions in case of unforeseen effects of the use of medical technology, pharmacological or medicinal product on state of health;
- 4) on conditions of health insurance.

At the same time, before the start of research, a volunteer or patient, legal representative of a minor, guardian of an incapacitated person must be informed about the possibility of refusing biomedical research at any stage of the research.

8. Biomedical research shall be terminated at any stage:

- 1) at the request of a minor participating in 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 volunteer or patient, a minor, or an incapacitated person.

9. Mandatory conditions for conducting biomedical research shall be a positive conclusion of the Commission on Bioethics, and for interventional clinical research, also the execution of documents on life and health insurance of the research participant.

10. The rules for conducting biomedical research and the requirements for research centers shall be determined by the authorized authority.

11. The rules for application of new methods of diagnosis, treatment and medical rehabilitation shall be determined by the authorized authority.

Footnote. Article 227 as amended by the Law of the Republic of Kazakhstan dated 30.12.2021 № 98-VII (shall be enforced upon expiry of sixty calendar days from the date of its first official publication).

#### **Article 228. Bioethics Commission**

1. The Bioethics Commission shall be an independent expert authority that conducts bioethical examination of documents related to the conduct of biomedical research, at the planning stage, during implementation and after completion in order to ensure the safety and protection of the rights of participants in biomedical research.

2. The Central Commission on Bioethics and local commissions on bioethics function in the Republic of Kazakhstan.

3. The Central Commission on Bioethics shall be created under the authorized authority to perform the following tasks:

1) analysis and informing specialists and the public on bioethics in the context of development of modern healthcare and the introduction of innovative medical technologies;

2) issuance of conclusions on conduct of interventional clinical trials of medicines, medical devices of foreign production, as well as interventional and non-interventional clinical trials of medicines, medical devices, conducted in two or more research centers located in the Republic of Kazakhstan;

3) implementation of bioethical monitoring over the course of biomedical research, for which the conclusion of the Central Commission on Bioethics and permission of the authorized authority were issued;

4) coordinating the activities of local bioethics commissions and assessing the compliance of their activities with the standards approved by the Central Bioethics Commission;

5) participation in development of documents on bioethics;

6) certification of local bioethics commissions.

4. Central and local commissions on bioethics shall be formed on an interdisciplinary basis and consist of representatives of the medical, humanitarian professions, public organizations and specialists in the field of law.

5. The composition and regulations on the Central Bioethics Commission shall be approved by the authorized authority.

6. Local commissions on bioethics shall be created at healthcare organizations to perform the following tasks:

1) issuance of conclusions on conducting biomedical research, except for the cases specified in Subparagraph 2) of Paragraph 3 of this Article;

2) implementation of bioethical monitoring of the progress of biomedical research, for which a conclusion was issued by this local commission on bioethics and permission of the authorized authority;

3) submission of an annual report to the Central Commission on Bioethics in the manner determined by it.

7. The composition and regulations on the local commission on bioethics shall be approved by the order of the first head of the healthcare organization, under which this commission shall be created, in agreement with the Central Commission on Bioethics.

8. Local commissions on bioethics have the right to issue conclusions on conducting biomedical research, subject to the availability of a certificate of compliance with the standards of activity of bioethics commissions issued by the Central Commission on Bioethics.

9. An appeal by an applicant who disagrees with the results of the bioethical examination shall be considered by a commission with the participation of the applicant himself and the involvement of independent experts.

10. The validity period of the certificate of conformity to the requirements of the activity of bioethical commissions and the procedure for its issuance shall be determined by the authorized authority.

#### **Article 229. Biobanks**

1. A biobank shall be created on the basis of a healthcare organization, an organization of higher and (or) postgraduate education and a scientific organization on the basis of a positive opinion of the Central Commission on Bioethics.

2. Biological materials stored in biobanks must be collected in accordance with the legislation of the Republic of Kazakhstan, bioethics standards in compliance with all requirements for sample preparation, transportation, laboratory processing and storage.

3. The procedure for creation and rules for the activities of biobanks shall be determined by the authorized authority.

### **SECTION 5. PHARMACEUTICAL ACTIVITY, CIRCULATION OF MEDICINES AND MEDICAL PRODUCTS**

#### **Chapter 27. PHARMACEUTICAL ACTIVITY**

##### **Article 230. Types of pharmaceutical activity**

Pharmaceutical activity includes the following types:

- 1) production of medicines;
- 2) production of medical products;
- 3) manufacturing of medicinal products;
- 4) manufacturing of medical devices;
- 5) wholesale of medicines;
- 6) wholesale of medical products;



- 7) retail sale of medicines;
- 8) retail sale of medical products.

### **Article 231. Production of medicines and medical products**

1. Production of medicines and medical products shall be a pharmaceutical activity, which includes the totality of all works required for the serial production of medicines and medical products associated with the acquisition of raw materials, materials, semi-finished products, equipment, components and a technological process, including the implementation of one of its stages, storage, sale of manufactured 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 entities in the field of circulation of medicines and medical products 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 prescribed by the legislation of the Republic of Kazakhstan.

Subjects in the field of circulation of medicines and medical products in production of medicines shall be required to comply with the requirements of good manufacturing practice (GMP).

3. Stability studies, determination of the shelf life and re-control of medical product shall be carried out by the manufacturer of the medical product in the manner determined by the authorized authority.

Stability studies, determination of the shelf life of medical products shall be conducted by the manufacturer of medical devices in accordance with international standards.

4. It shall be prohibited to manufacture medicines and medical products:

1) that have not passed state registration in the Republic of Kazakhstan, except for medicines and medical products intended for examination during their state registration, debugging and launching equipment and technological processes, preclinical (nonclinical) and clinical trials, contract production and production for export of medicinal means and medical products, as well as medicines of advanced therapy, produced for individual use using autologous biological materials of the patient or his donor, selected directly for him;

2) without a license for the right to manufacture medicines and medical products;

3) in violation of good manufacturing practices and rules for production of medical products.

5. Manufactured and imported medical products:

1) must not contain dyes and auxiliary substances prohibited for use in the Republic of Kazakhstan, the list of which shall be approved by the authorized authority;

2) must be subject to control in accordance with the regulatory document on the quality of medicines developed by the producer of medicines and agreed by the state expert organization for examination of medicines in the manner determined by the authorized authority;

3) must be made from a pharmaceutical substance (active pharmaceutical ingredient) produced under conditions not lower than the requirements of good manufacturing practice (GMP) of the Republic of Kazakhstan and (or) the Eurasian Economic Union and declared during state registration, re-registration and amendments to the registration dossier of medicines.

Medicines produced in the territory of the Republic of Kazakhstan only for export shall not be subject to state registration and sale in the Republic of Kazakhstan.

6. Produced and imported medical products must be subject to control in accordance with the regulatory document of a medical product submitted by the producer of a medical device during the examination of a medical device for the purpose of state registration, re-registration and amendments to the registration dossier of a medical product.

Medical products produced in the territory of the Republic of Kazakhstan only for export shall not be subject to state registration and sale in the Republic of Kazakhstan.

7. The production and sale of patented medicines and medical products shall be carried out in accordance with the legislation of the Republic of Kazakhstan.

8. The production of medical products intended for diagnostics or treatment should ensure their safety, provide for their use in accordance with their functional purpose and exclude the approach of user errors when interpreting the results of diagnostics or treatment.

9. The producer of medical products shall ensure the presence in the staff of at least one authorized person of the producer who is responsible for fulfilling duties in accordance with the requirements of good producing practice (GMP) of the Republic of Kazakhstan and (or) the Eurasian Economic Union.

#### **Article 232. Production of medicines and medical products**

Production of medicines and medical products shall be carried out by entities in the field of circulation of medicines and medical products that are licensed to manufacture medicines and medical products in the manner determined by the authorized authority. Produced medical products shall be subject to intra-pharmacy control in the manner determined by the authorized authority.

#### **Article 233. Wholesale and retail trade of medicines and medical products**

1. Wholesale of medicines and medical products shall be carried out by entities in the field of circulation of medicines and medical products that have received an appropriate license for wholesale in pharmacy warehouses or notified about the start of activities through a warehouse of medical products in the manner prescribed by the Law of the Republic of Kazakhstan "On permits and notifications".

2. Retail sale of medicines and medical products shall be carried out by entities in the field of circulation of medicines and medical products that have received an appropriate

license for retail sale in pharmacies, pharmacies, mobile pharmacies or notified of the start of activities through optical stores and medical products in the manner prescribed the Law of the Republic of Kazakhstan "On Permits and Notifications".

3. Subjects in the field of circulation of medicines and medical products that carry out retail sale of medicines shall be obliged to comply with the requirements of Good Pharmacy Practice (GPP).

Entities in the field of circulation of medicines and medical devices engaged in the wholesale sale of medicines are obliged to comply with the requirements of good distribution practice (GDP).

Subjects in the field of circulation of medicines and medical products that have received a license or notified about the start of activities in the manner prescribed by the Law of the Republic of Kazakhstan "On permits and notifications" shall be allowed wholesale and retail sale of goods not related to medicines and medical products in accordance with the list approved by the authorized authority.

4. Wholesale and retail sales of medicines and medical products shall be prohibited:

- 1) those who have not passed state registration in the Republic of Kazakhstan;
- 2) the quality of which is not confirmed by a certificate of conformity in the manner established by the legislation of the Republic of Kazakhstan in the field of healthcare;
- 3) do not meet the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare;
- 4) expired;
- 5) by medical workers in healthcare organizations, with the exception of the retail sale of medicines and medical devices in rural settlements in the cases provided for in paragraph 6 of this article;
- 6) through warehouses for temporary storage of medicines and medical products.

4-1. The wholesale and retail sale of bulk products of medicines or medical products is prohibited, with the exception of the wholesale sale of bulk products of medicines or medical products used by entities in the field of circulation of medicines and medical products for the production of medicines.

5. OTC sales of medicinal products intended for dispensing with a doctor's prescription shall be prohibited. Prescriptions shall be issued in paper and (or) electronic form.

The shelf life of a paper prescription for a medical product shall be at least thirty calendar days, except for a prescription for a medical product containing narcotic drugs, psychotropic substances, precursors and poisonous substances, which shall be stored for one year, for a medicinal product dispensed within the guaranteed scope of free medical care and (or) compulsory social health insurance, the storage period of which shall be two years.

The rules for classifying medical products, taking into account the active substances in their composition, to the categories of medical products sold without a prescription and

prescription, the rules for prescribing, recording and storing prescriptions shall be approved by the authorized authority.

6. In rural settlements where there are no pharmacies, the sale of medicines and medical products can be carried out by individuals and legal entities through pharmacy points in healthcare organizations providing primary health care, consultative and diagnostic assistance, and mobile pharmacy points. In the absence of pharmacy points, the retail sale of medicines and medical products can be carried out through healthcare organizations providing primary health care, consultative and diagnostic assistance. In the absence of specialists with pharmaceutical education for the retail sale of medicines and medical products, specialists with medical education who have been trained for their sale are allowed.

7. Medicines and medical products imported and produced in the territory of the Republic of Kazakhstan before the expiration of the registration certificate shall be used, circulated and operated in the territory of the Republic of Kazakhstan without restrictions.

**Footnote. Article 233 as amended by the Laws of the Republic of Kazakhstan dated 27.06.2022 № 129-VII (shall be enforced ten calendar days after the date of its first official publication); dated 04.07.2022 № 134-VII (shall be enforced sixty calendar days after the date of its first official publication).**

## **Chapter 28. CIRCULATION OF MEDICINES AND MEDICAL PRODUCTS**

### **Article 234. System of the sphere of circulation of medicines and medical products**

The unified system of the sphere of circulation of medicines and medical products includes:

- 1) the state authority in the field of circulation of medicines and medical products and its territorial divisions;
- 2) the state expert organization in the field of circulation of medicines and medical products and its territorial divisions;
- 3) subjects in the field of circulation of medicines and medical products.

### **Article 235. Development of medicines and medical products**

1. Development of medicines includes the search 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. The development of medicines shall be carried out in compliance with the requirements of good pharmaceutical practices to ensure their safety and effectiveness.

3. Development of medical products includes the search and (or) creation of a technical solution, invention, design, construction and testing of prototypes, as well as the development of technologies for industrial production of medical products.

4. Development of medical products shall be carried out in compliance with the requirements of international standards to ensure their safety and effectiveness.

5. The rights of the developer of the medicines and medical product shall be protected by the legislation of the Republic of Kazakhstan.

**Article 236. Preclinical (nonclinical) studies of medicines and studies (tests) evaluating the biological effect of medical products**

1. The purpose of preclinical (nonclinical) studies of medicines shall be to obtain scientific evidence of their pharmacological activity and safety.

Studies (tests) evaluating the biological effect of medical products shall be carried out to determine the acceptability of any potential adverse biological response resulting from the contact of medical product materials with the human body.

2. The procedure for conducting preclinical (nonclinical) studies and requirements for preclinical bases for assessing the biological effect of medical products shall be determined by the authorized authority.

Preclinical (non-clinical) studies shall be carried out in accordance with good laboratory practice (GLP) of the Republic of Kazakhstan and (or) the Eurasian Economic Union.

Assessment of materials and compliance of the conditions for conducting preclinical (nonclinical) studies with the requirements of good laboratory practice (GLP) of the Republic of Kazakhstan and (or) the Eurasian Economic Union shall be carried out within the pharmaceutical inspection in the manner determined by the authorized authority.

**Article 237. Technical tests of medical products**

1. Technical tests of medical products shall be carried out in the form of tests and (or) evaluation and analysis of data to verify the quality and safety when used in accordance with the purpose provided by the documentation of the manufacturer of the medical product.

2. Technical tests of medical products shall be carried out in organizations accredited to conduct technical tests in the manner determined by the legislation of the Republic of Kazakhstan in the field of technical regulation.

3. The procedure for conducting technical tests shall be determined by the authorized authority.

**Article 238. Clinical studies of medicines, medical products and clinical and laboratory tests of medical products for diagnostics outside a living organism (in vitro)**

1. Clinical studies of medicines and medical products shall be carried out with the participation of a person as a subject to identify or confirm the clinical and (or) pharmacodynamic effects of the investigated pharmacological or medicines and (or) identify adverse reactions and (or) in order to study absorption, distribution, biotransformation and

excretion of drugs, assessing the safety and (or) functional characteristics of medical products and (or) adverse events of a medical product to establish safety and efficacy.

Clinical and laboratory tests of medical products for diagnostics outside a living organism (in vitro) shall be carried out for analytical characteristics, clinical effectiveness (if applicable ) to establish the compliance of a medical product for diagnostics outside a living organism ( in vitro).

2. Clinical studies shall be carried out in accordance with the rules of good clinical practice (GCP) of the Republic of Kazakhstan and (or) the Eurasian Economic Union.

3. Accelerated examination of clinical studies (hereinafter referred to as the accelerated procedure) shall be carried out for medicines:

1) designed to prevent emergencies;

2) orphan drugs;

3) medicines of advanced therapy produced for individual use using autologous biological materials from the patient or his donor, selected directly for him.

4. When carrying out the accelerated procedure, the requirements for the safety, efficacy and quality of medicines shall not be reduced.

5. The applicant provides substantiated evidence of the need for and the possibility of carrying out an examination according to the accelerated procedure, confirmed by the authorized authority.

6. The procedure for conducting clinical studies of medicines and medical products, clinical and laboratory tests of medical products for diagnostics outside a living organism (in vitro) and requirements for clinical bases shall be determined by the authorized authority.

### **Article 239. Expertise of medicines and medical products**

1. Expertise of medicines and medical products shall be a comprehensive assessment of safety, quality and efficacy, the benefit-risk ratio, the assessment of materials for clinical studies of medicines and medical products, the assessment of the optimal technical characteristics and clinical and technical justification of a medical product, carried out at the materials of the registration dossier, laboratory tests for compliance with regulated quality, pharmacovigilance data, monitoring the safety, quality and effectiveness of medical products, materials for evaluating clinical studies, materials for evaluating the optimal technical characteristics and clinical and technical justification of a medical product.

2. Expertise of medicines and medical products belongs 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 (work, services) produced and (or) sold by a state monopoly entity shall be established by the authorized authority in agreement with the antimonopoly authority.

3. Requirements for the safety, quality and efficacy of pharmaceutical substances (active pharmaceutical ingredients), medicinal raw materials, medicinal plant raw materials, bulk

products of medicines or medical products, original medicinal products, medicinal products of biological origin, biotechnological medicinal products, immunological medicinal products (immunobiological medicinal products), reproduced medicinal products (generics), homeopathic medicinal products, biosimilar medicinal products (biosimilars, biosimilar medicinal products, biosimilars) and medical products shall be presented during the expertise of medicines and medical products in the manner determined by the authorized authority.

4. The grounds for a negative conclusion of the expertise of medicines and medical products shall be:

1) failure to submit a complete set of registration dossier after the issuance of comments to the applicant during the expertise process within the time frame established in the manner determined by the authorized authority;

2) submission by the applicant of false information;

3) the ratio of the expected benefit to the possible risks associated with the use of the medicinal product shall not be favorable;

4) lower quality and safety indicators regulated by the State Pharmacopoeia of the Republic of Kazakhstan or pharmacopoeias recognized as valid in the territory of the Republic of Kazakhstan, or in comparison with previously registered analogues;

5) presence in the composition of the medicines of substances and materials prohibited for use in the Republic of Kazakhstan;

6) presence of preservatives in solid dosage forms;

7) obtaining negative results of one of the stages of examination and (or) negative opinions of experts from specialized organizations;

8) inconsistency of the actual production conditions and the quality assurance system with the conditions ensuring the declared safety, efficiency and quality, based on the results of the quality assurance system assessment;

9) the applicant's refusal to organize a visit to the enterprise (production site) in order to assess the quality assurance system in accordance with the requirements of the legislation of the Republic of Kazakhstan;

10) identification of irrational medicines combinations;

11) the applicant has not proven the clinical efficacy and safety of the medicinal product;

12) the quality of the medicinal product has not been confirmed;

13) a proven unfavorable benefit-risk ratio or a revealed lack of therapeutic efficacy, subject to the conditions of use of the medicinal product described in the approved general characteristics of the medicinal product in the post-registration period;

14) facts established according to pharmacovigilance data indicating an unfavorable benefit-risk ratio of medicines, including an excess of the frequency of reporting adverse reactions in comparison with the data specified in the approved general characteristics of the medicinal product;

15) inconsistency of the qualitative and quantitative composition of the drug with the declared one or repeated inconsistency of the quality of the medicinal product during the period of its circulation on the market with the declared one at the time of its registration;

16) failure of the holder of the marketing authorization to fulfill the obligations of pharmacovigilance;

17) the changes introduced have a negative impact on the benefit-risk ratio of medicinal product.

#### **Article 240. State Pharmacopoeia of the Republic of Kazakhstan**

1. The quality and safety of medicines and medical products 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 the peculiarities of development of pharmaceutical market of the Republic of Kazakhstan.

3. In the absence of relevant articles (monographs) in the State Pharmacopoeia of the Republic of Kazakhstan, the current editions of the world's leading pharmacopoeias, recognized by the authorized authority, shall be applied.

4. General articles of the State Pharmacopoeia of the Republic of Kazakhstan determine general requirements for:

- 1) quality of pharmaceutical substances (active pharmaceutical ingredients), medicines;
- 2) reagents, reference materials, methods and test procedures used to control their quality;
- 3) packaging materials and containers.

5. Private articles of the State Pharmacopoeia of the Republic of Kazakhstan define specific requirements for quality of pharmaceutical substances (active pharmaceutical ingredients), 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 amendments 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 products.

The procedure for development, registration, agreement, approval and introduction of amendments and additions to the State Pharmacopoeia of the Republic of Kazakhstan shall be determined by the authorized authority.

8. The State Pharmacopoeia of the Republic of Kazakhstan in terms of structure, design of monographs, numbering of sections and pharmacopoeial articles (monographs), symbols,



representation of formulas must correspond to the leading pharmacopoeias of the world recognized by the authorized authority.

#### **Article 241. Assessment of quality of medicines and medical products registered in the Republic of Kazakhstan**

1. Assessment of quality of medicines and medical products registered in the Republic of Kazakhstan shall be carried out by determining the compliance of quality of medicines and medical products with the data of the registration dossier, regulatory documents on quality of medicines, on the basis of which they were registered in the Republic of Kazakhstan.

2. Assessment of quality of medicines and medical products registered in the Republic of Kazakhstan belongs 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 (work, services) produced and (or) sold by a state monopoly entity shall be established by the authorized authority in agreement with the antimonopoly authority.

#### **Article 242. Labeling of medicines and medical products**

1. Medicines must be put into circulation with labeling applied to the packaging (primary and (or) secondary) in a well-readable font in Kazakh and Russian, and instructions for medical use (leaflet) in Kazakh and Russian.

Labeling texts and instructions for medical use (leaflet) must comply with the requirements of the Law of the Republic of Kazakhstan “On languages in the Republic of Kazakhstan”.

2. For medical workers on the Internet resources of the authorized authority and the state expert organization in the field of circulation of medicines and medical products, the general characteristics of the medicine, approved during state registration, shall be posted.

3. Medical products must be put into circulation with a label applied directly to medical devices and (or) packaging, and instructions for medical use or an operational document for a medical device in Kazakh and Russian.

Labeling texts, instructions for medical use or an operational document for a medical product must comply with the requirements of the Law of the Republic of Kazakhstan “On languages in the Republic of Kazakhstan”.

4. Rules for labeling medicines and medical products shall be approved by the authorized authority.

The procedure for preparation and execution of instructions for medical use of medicines and medical products, the general characteristics of medicine shall be determined by the authorized authority.

Footnote. Article 242 as amended by the law of the Republic of Kazakhstan dated 29.12.2021 № 94-VII (shall be enforced upon expiry of ten calendar days after the date of its first official publication).

### **Article 243. Use of medicines of advanced therapy**

1. Medicines of advanced therapy, according to the method of production and use, shall be divided into:

- 1) industrially produced (routine method) in a pharmaceutical production on a batch basis;
- 2) produced for individual use using autologous biological materials of the patient or his donor, selected directly for him.

2. The procedure for admission to the use, use and monitoring of effectiveness and safety of use of medicines of advanced therapy shall be determined by the authorized authority.

3. Medicines of advanced therapy shall be subject to clinical trials in accordance with the procedure established in Article 238 of this Code.

4. Medicines of advanced therapy, produced in an industrial environment, in respect of which positive results of clinical studies have been obtained, for admission to the market of medical services shall be subject to state registration in accordance with the procedure for State registration of a medicines or medical product established by Article 23 of this Code.

5. Medicines of advanced therapy, produced for individual use, in respect of which positive results of clinical studies have been obtained, shall be admitted to the market of medical services on the basis of conclusion of an expert organization in the field of circulation of medicines and medical products without the state registration procedure.

6. In exceptional cases, medicines of advanced therapy manufactured for individual use shall be used without conducting clinical trials as part of an exclusion from the standard procedure for marketing a medicinal product, provided:

- 1) presence of a positive conclusion of the local Commission on Bioethics;
- 2) scientific reason to expect that the use of medicines of advanced therapy will directly benefit the patient;
- 3) obtaining the informed consent of the patient or his legal representative for use of medicines of advanced therapy.

The doctor prescribing the medicines of advanced therapy ensures that the specified conditions shall met and, based on the results of use of the medicines of advanced therapy, as part of the exclusion from the standard procedure for marketing the medicines, submits a report to the state expert organization in the field of circulation of medicines and medical products and the Bioethics Commission.

7. The procedure for use of medicines of advanced therapy under exemption from the standard procedure for release of medicines on the market, as well as the list of medical organizations eligible for treatment under the Hospital exemption, shall be determined by the authorized authority.

## **Article 244. Pharmaceutical Inspectorate for Good Pharmaceutical Practices**

1. Pharmaceutical Inspectorate for Good Pharmaceutical Practices - structural subdivisions of the state authority in the field of circulation of medicines and medical products, its territorial divisions and (or) an organization determined by the authorized authority that inspects compliance with good pharmaceutical practices for medicines and requirements for implementation, maintaining and evaluating the quality management system of medical products, depending on the potential risk of their use.

2. The state authority in the field of circulation of medicines and medical products coordinates the activities of the Pharmaceutical Inspectorate for Good Pharmaceutical Practices.

The state authority in the field of circulation of medicines and medical products and its territorial divisions issue or revoke certificates (opinions) for compliance with the requirements of good pharmaceutical practices.

3. Pharmaceutical inspection shall be carried out in the following cases:

1) on the basis of an application from entity in the field of circulation of medicines and medical products for obtaining a certificate (opinion) or renewal of its validity, as well as in accordance with good Pharmacovigilance Practice (GVP);

2) on the basis of an application by entity in the field of circulation of medicines and medical products, as well as for the purpose of licensing, registration, re-registration, examination of medicines or conducting investigations related to the safety, quality and efficacy of medicines in accordance with the pharmaceutical inspection program;

3) based on the results of a previously conducted pharmaceutical inspection in order to confirm the elimination of the identified inconsistencies;

4) for confirmation by entities that have received a certificate confirming the compliance of the facility with the requirements of Good Pharmaceutical Practices in the field of drug circulation (hereinafter referred to as the certificate), at least once every two years in accordance with the inspection schedule approved by the head of the state authority in the field of circulation of medicines and medical products;

5) according to Good Clinical Practice shall be carried out in the following cases:

revealing, during the examination of clinical reports related to the registration of a medicines, facts that cast doubt on the reliability of the information provided by the applicant in the registration dossier in relation to clinical studies (tests) of medicines;

before, during or after the completion of clinical studies of medicines, medical products of potential risk classes 3, 2b and implantable medical products;

inspection of the pharmacovigilance system of the marketing authorization holder in cases provided by the rules of good Pharmacovigilance Practice of the Republic of Kazakhstan and (or) the Eurasian Economic Union.

4. The validity period of the certificate of compliance of the object with the requirements:

- 1) Good Manufacturing Practice (GMP) - three years;
- 2) Good Distribution Practice (GDP), Good Laboratory Practice (GLP) - three years;
- 3) Good Pharmacy Practice (GPP) - the first two times for five years, upon subsequent confirmation - indefinitely.

5. Pharmacies shall be subject to pharmaceutical inspection for compliance with the requirements of Good Pharmacy Practice (GPP), pharmacy (distribution) warehouses - for compliance with the requirements of Good Distribution Practice (GDP), medicines production organizations - for compliance with the requirements of Good Manufacturing Practice (GMP), organizations, carrying out preclinical (non-clinical) studies - for compliance with the requirements of good laboratory practice (GLP), clinical studies carried out by healthcare organizations - for compliance with the requirements of good clinical practice (GCP), holders of drug registration certificates - for compliance with the requirements of good pharmacovigilance practice (GVP).

6. Pharmaceutical inspections shall be carried out in the manner determined by the authorized authority.

7. Within the pharmaceutical inspection, selection and examination, assessment of safety and quality of medicines may be carried out.

8. The conditions of storage and transportation of selected samples of medicinal products should not change the parameters by which the examination, safety and quality assessment of these samples of medicinal products will be carried out.

The pharmaceutical inspector for Good Pharmaceutical Practices ensures the safety of medicines samples and timely delivery to the place of examination, safety and quality assessment.

9. Inspections of medical products shall be carried out in accordance with the requirements for implementation, maintenance and assessment of the quality management system of medical products, depending on the potential risk of their use in the manner determined by the authorized authority.

10. During a state of emergency, in accordance with the Law of the Republic of Kazakhstan "On emergency state", pharmaceutical inspections for investigations related to the safety, quality and efficacy of medicines shall be carried out by decision of the state authority in the field of circulation of medicines and medical products.

#### **Article 245. State regulation of prices for medicines and medical products**

1. State regulation of prices shall be carried out for medicines registered and in circulation in the Republic of Kazakhstan for wholesale and retail sales, included in the list of medicines subject to price regulation, as well as for registered medicines and medical products within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance in the manner determined by the authorized body.

The list of medicines subject to price regulation for wholesale and retail sales shall be approved by the authorized body no more than once every six months no later than the tenth day of the third month of the six months in agreement with the antimonopoly authority.

2. The authorized body shall, no more than once every half a year, no later than the tenth day of the first month of the half year, approve, in agreement with the antimonopoly body, the manufacturer's maximum prices for the medicine trade name, the maximum prices for the medicine trade name for retail and wholesale sales, included in the list of medicines subject to price regulation.

3. The authorized body shall approve the maximum price for the trade name of a medicine or medical device within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance in agreement with the antimonopoly authority, the maximum price for the international generic name of a medicine or the technical characteristics of a medical product within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance.

4. The authorized authority on an ongoing basis keeps records and systematization of the information specified in Paragraphs 2 and 3 of this Article in electronic form in chronological order, taking into account the changes made and preserving previous versions and providing the possibility of open access to this information in electronic.

The information specified in Paragraphs 2 and 3 of this Article shall be stored for five years, starting from the year following the year of approval of the maximum prices for medicines.

5. The maximum retail price cannot be approved without observing the total wholesale and retail mark-up to the manufacturer's maximum price.

6. The authorized authority monitors and controls compliance with the marginal prices of medicines by trade names.

7. Wholesale and retail sale of medicines included in the list of medicines subject to price regulation shall not be allowed without a maximum price for medicines by trade names.

**Footnote. Article as amended by the law of the Republic of Kazakhstan dated 03.01.2022 № 101-VII (shall be enforced upon expiry of sixty calendar days from the date of its first official publication); dated 04.07.2022 № 134-VII (shall be enforced sixty calendar days after the date of its first official publication).**

#### **Article 246. Procurement of medicines and medical products intended for provision of minimum, basic and additional scopes of medical care**

1. Medicines intended to provide minimal, basic and additional volumes of medical care shall be purchased under international non-proprietary names, and in case of individual intolerance of the patient - under the trade names of medicines registered in the Republic of Kazakhstan, based on the conclusion of the medical advisory commission and the decision of the local representative authority of the region, cities of republican significance and the

capital. In the case of the purchase of multicomponent medicine, its composition shall be indicated.

2. For the purpose of optimal and efficient spending of budgetary funds allocated for procurement of medicines and medical products within the guaranteed scope of free medical care, and compulsory social medical insurance funds, medicines and medical products shall be procured at prices not exceeding those established by the authorized authority, except for unregistered medicines and medical products imported into the territory of the Republic of Kazakhstan on the basis of an opinion (permitting document) issued by the authorized authority.

3. The procurement of medicines and medical products intended for provision of the guaranteed scope of free medical care and (or) medical care in the system of compulsory social health insurance shall be carried out in the manner and methods established by the Government of the Republic of Kazakhstan, including through the web portal for procurement of medicines and medical products, procurement of services from healthcare entities.

4. The preferential right to conclude contracts within the guaranteed scope of free medical care and (or) in the system of compulsory social health insurance have subjects in the field of circulation of medicines and medical products, including pharmacies with the right to manufacture medicines, having a certificate of conformity of the object requirements:

1) Good Manufacturing Practice (GMP), when purchasing drugs and concluding long-term contracts for supply of medicines;

2) Good Distribution Practice (GDP), when purchasing medicines, pharmaceutical services and concluding long-term contracts for storage and transportation of medicines and medical products;

3) Good Pharmacy Practice (GPP), in procurement of pharmaceutical services, services for registration and sale of medicines and medical products.

**Footnote. Article 246 as amended by the Law of the Republic of Kazakhstan dated 03.01.2022 № 101-VII (shall be enforced upon expiry of sixty calendar days from the date of its first official publication).**

#### **Article 247. National Distributor**

The main scope of operation of the national distributor shall be:

1) selection of suppliers;

2) conclusion of agreements for delivery of pharmaceutical products and medical products, as well as for delivery and production of plasma-based blood preparations, including those industrial, within contractual fractionation;

3) conclusion of long-term agreements for delivery of pharmaceutical products and medical products, as well as for production and delivery of plasma-based blood preparations,

including within contractual fractioning, as well as on production of plasma-based blood preparations (contractual fractioning) from producers, including from international producers;

4) provision of pharmaceutical products and medical products as per a list determined by the authorized body;

5) procurement of pharmaceutical products and medical products, plasma-based blood preparations, including within contractual fractioning, services on storage and transportation as per list determined by the authorized body, as well as services on production of plasma-based blood preparations (contractual fractioning) from producers, including from international producers;

6) procurement of pharmaceutical services;

7) procurement on accounting and sale of pharmaceutical products and medical products;

8) organization of procurement of medical products within statutory free medical assistance;

9) delivery, storage of pharmaceutical products and medical products of mobilization reserve, and issue thereof in order to replenish and cancel reservation in case of changed assortment stipulated by the laws of the Republic of Kazakhstan on civil protection.

#### **Article 248. Principles for procurement of pharmaceutical products and medical products by the national distributor**

The principles for procurement of pharmaceutical products and medical products are:

1) provision of potential suppliers with equal opportunities for participation in procurement procedure;

2) fair competition among potential suppliers;

3) publicity and transparency of procurement process;

4) support for national manufacturers.

#### **Article 249. Powers of the national operator**

The national operator:

1) administers establishment, development, support and system and technical maintenance of the web portal for procurement of pharmaceutical products and medical products, services from public healthcare entities;

2) administers management of projects on development of the web portal for procurement of pharmaceutical products and medical products, services from public healthcare entities;

3) provides public healthcare entities with services on the use of the web portal for procurement of pharmaceutical products and medical products, services from public healthcare entities;

4) provides advisory assistance to public healthcare entities on issues of operation of the web portal for procurement of pharmaceutical products and medical products, services from public healthcare entities;

5) maintains information security of storage of information resources of entities of the state procurement system, placed on the web portal for procurement of pharmaceutical products and medical products, services from public healthcare entities;

6) provides information content for the web portal for procurement of pharmaceutical products and medical products, services from public healthcare entities;

7) interacts with authorized entities on issues of integration of information systems of government bodies, government electronic information resources and maintenance of information security.

#### **Article 250. Storage, transportation and elimination of pharmaceutical products and medical products**

1. Pharmaceutical products and medical products shall be stored and transported in conditions ensuring maintenance of their safety, quality and efficiency in accordance with the regulations on storage and transportation of pharmaceutical products and medical products approved by the authorized body.

2. It is prohibited to extend shelf life of pharmaceutical products and medical products.

3. Entities in the field of circulation of pharmaceutical products and medical products, administering transportation and storage of pharmaceutical products, must meet the requirements of Good Distribution Practice (GDP) or Good Pharmacy Practice (GPP).

4. Pharmaceutical products and medical products, which are unfit for use, with expired shelf life, falsified pharmaceutical products or medical products and others not meeting the requirements of the laws of the Republic of Kazakhstan shall be considered unfit for sale and medical use, and shall be subject to elimination by entities in the field of circulation of pharmaceutical products and medical products, in the possession whereof they are, in accordance with the procedures determined by the authorized body.

#### **Article 251. Procedures for importing of pharmaceutical products and medical products to the Republic of Kazakhstan**

1. Import to the Republic of Kazakhstan of pharmaceutical products and medical products shall be in accordance with the procedures determined by the authorized body as per customs laws of the Republic of Kazakhstan and (or) international agreements and instruments in the field of customs regulation of Eurasian Economic Union.

It shall be allowed to import medicines registered in the Republic of Kazakhstan, using stickers with a well-readable font in Kazakh and Russian languages and medical products registered in the Republic of Kazakhstan, using stickers in Kazakh and Russian languages and



with instructions for medical use (leaflet) or an instruction for medical use or an operational document for a medical product in the Kazakh and Russian languages for their sale below the approved limit wholesale and retail prices in the Republic of Kazakhstan in accordance with the procedure, determined by the authorized body.

The texts of stickers, instructions for medical use (leaflet), instructions for medical use or an operational document for a medical device must comply with the requirements of the Law of the Republic of Kazakhstan “On languages in the Republic of Kazakhstan”.

2. It is prohibited to import to the Republic of Kazakhstan pharmaceutical products and medical products, which have not passed state registration in the Republic of Kazakhstan, except for cases specified in paragraph 3 of this article and article 253 of this Code.

3. It is allowed to import to the Republic of Kazakhstan pharmaceutical products and medical products not registered in the Republic of Kazakhstan on the basis of a conclusion (authorization document) issued by the authorized body, when they are intended for:

- 1) conduction of clinical examination;
- 2) expert evaluation of pharmaceutical products and medical products at state registration, re-registration and introduction of amendments to registration dossiers;
- 3) state registration of pharmaceutical products and medical products;
- 4) delivery of emergency healthcare services for a certain patient or delivery of healthcare services to a limited contingent of patients with rare and (or) extra severe pathology with an opportunity of medical application and procurement;
- 5) holding of exhibitions without a right for further sale;
- 6) humanitarian aid (assistance), prevention and (or) elimination of emergency consequences;
- 7) adoption of innovative medical technology;
- 8) procurement by the national distributor of pharmaceutical products and medical products, supplied by international organizations, established by the United Nations General Assembly, and (or) re-categorized by the World Health Organization, except for pharmaceutical products and medical products within long-term agreements for delivery of pharmaceutical products and medical products;
- 9) use as a component included in the composition or structure of a medical product and not designed for independent use beyond the composition or structure of a medical product;
- 10) prevention and treatment of consequences of influence of radioactive, biological or chemical materials (vaccines, antidote).

4. It is prohibited to import to the Republic of Kazakhstan pharmaceutical products and medical products, which have not passed state registration, as humanitarian aid, except for separate cases to be defined by the authorized body.

5. Pharmaceutical products and medical products imported to the Republic of Kazakhstan, failing to meet the requirements of the laws of the Republic of Kazakhstan in the field of public health, are subject to confiscation and elimination.

Footnote. Article 251 as amended by the law of the Republic of Kazakhstan dated 29.12.2021 № 94-VII (shall be enforced upon expiry of ten calendar days after the date of its first official publication).

**Article 252. Persons allowed to import pharmaceutical products and medical products to the Republic of Kazakhstan**

Pharmaceutical products and medical products to the Republic of Kazakhstan may be imported:

1) by entities in the field of circulation of pharmaceutical products and medical products, having license for production of pharmaceutical products and medical products;

2) entities in the field of circulation of pharmaceutical products and medical products, having license for wholesale trading of pharmaceutical products or those included in the register of entities of public health services, administering wholesale trading of medical products, upon notification of commencement of business;

3) research organizations, laboratories for development and state registration of pharmaceutical products and medical products in accordance with this Code;

4) international manufacturers of pharmaceutical products and medical products, their authorized representative offices (branches) or their authorized individuals or legal entities for conduction of expert evaluation at state registration, clinical examinations and (or) testing and for participation in exhibition of manufacturers of pharmaceutical products and medical products in the Republic of Kazakhstan;

5) public healthcare organizations for implementation of medical activities.

**Article 253. Import of pharmaceutical products and medical products, as well as biological material for pre-clinical (non-clinical) and clinical examinations, reference materials of pharmaceutical substances (active pharmaceutical ingredients) and their admixtures to the Republic of Kazakhstan for personal use and other non-commercial purposes**

1. Pharmaceutical products and medical products shall be imported to the Republic of Kazakhstan without permit from the authorized body, when they are intended for:

1) personal use by individuals;

2) treatment of passengers and members of transport crews, train crews and drivers of vehicles arriving to the customs area of Eurasian Economic Union;

3) treatment of participants of international cultural, sporting events and participants of international expeditions.

2. In cases provided for by paragraph 1 of this article, it is allowed to import to the Republic of Kazakhstan pharmaceutical products and medical products not registered in the Republic of Kazakhstan.

3. Biological material for pre-clinical (non-clinical) and clinical examinations, reference materials of pharmaceutical substances (active pharmaceutical ingredients) their admixtures shall be imported to the Republic of Kazakhstan without permit from the authorized body.

4. Biological material for pre-clinical (non-clinical) and clinical examinations, reference materials for pharmaceutical substances (active pharmaceutical ingredients) and their admixtures shall be imported to the Republic of Kazakhstan:

- 1) by manufacturers of pharmaceutical products and medical products;
- 2) international manufacturers of pharmaceutical products and medical products, their authorized representative offices (branches) or their authorized individuals and legal entities;
- 3) research organizations, laboratories in the field of public healthcare, education and science.

#### **Article 254. Interaction of the authorized body and an authorized body in the field of customs affairs**

1. In conveying across customs border of Eurasian Economic Union, which coincide with the State Border of the Republic of Kazakhstan, pharmaceutical products and medical products, an authorized body in the field of customs affairs shall receive details, confirmed by the authorized body, on state registration of each imported pharmaceutical product or medical product with indication of date and number of state registration, except for cases, provided for by subparagraphs 3 and 4 article 251 and article 253 of this Code.

2. An authorized body in the field of customs affairs shall present to the authorized body details on import to the Republic of Kazakhstan across the customs border of Eurasian Economic Union, which coincide with the State Border of the Republic of Kazakhstan, and on export from the Republic of Kazakhstan across the customs border of Eurasian Economic Union, which coincide with the State Border of the Republic of Kazakhstan, of pharmaceutical products and medical products.

#### **Article 255. Procedures for import of pharmaceutical products and medical products, as well as biological material for pre-clinical (non-clinical) and clinical examinations, reference materials of pharmaceutical substances (active pharmaceutical ingredients) and their admixtures from the Republic of Kazakhstan**

1. Export of pharmaceutical products and medical products from the Republic of Kazakhstan shall be in accordance with the procedures determined by the authorized body.

2. Pharmaceutical products and medical products may be exported from the Republic of Kazakhstan without approval of the authorized body:

- 1) for personal use by individuals, leaving the Republic of Kazakhstan, at the amount required for a treatment course;
- 2) as a part of first aid kit;
- 3) exhibits imported upon permit of the authorized body for holding of exhibitions;

4) medical products imported for conduction of pre-clinical (non-clinical) or clinical examinations;

5) as part of medical first-aid kits used by military personnel and employees of special state bodies, according to the list determined by state bodies in coordination with the authorized body.

3. Pharmaceutical products and medical products from the Republic of Kazakhstan as a part of facilities of medical and search-and-rescue organizations and units leaving the Republic of Kazakhstan to participate in emergency management, shall be exported in accordance with the procedures determined by the authorized body.

4. Biological material for pre-clinical (non-clinical) and clinical examinations, reference materials for pharmaceutical substances (active pharmaceutical ingredients) and their admixtures shall be exported from the Republic of Kazakhstan:

1) by manufacturers of pharmaceutical products and medical products;

2) international manufacturers of pharmaceutical products and medical products, their authorized representative offices (branches) or their authorized individuals and legal entities;

3) research organizations, laboratories in the field of public healthcare, education and science.

**Footnote. Article 255 as amended by the Law of the Republic of Kazakhstan dated 19.04.2023 № 223-VII (shall be enforced ten calendar days after the date of its first official publication).**

#### **Article 256. Installation, repair, technical and metrological maintenance of medical equipment**

1. Installation, repair, technical and metrological maintenance of medical equipment shall be performed by individuals or legal entities having a right to perform such works in accordance with the laws of the Republic of Kazakhstan.

2. Level of safety of medical equipment after repair shall not be lower the level of safety established by technical certificate for medical products.

3. Organization of metrological support for measuring instruments of medical purpose, operated at healthcare organizations, shall be regulated in accordance with the laws of the Republic of Kazakhstan on measurement assurance.

4. Medical equipment, which is a measurement instrument, is subject to entering to the register of the state system for ensuring uniform measurement of the Republic of Kazakhstan and shall be approved for use in accordance with the laws of the Republic of Kazakhstan on measurement assurance.

List of medical equipment, which is a measurement instrument, shall be approved by the authorized body upon agreement with an authorized body exercising state control in the field of technical regulation and metrology.

#### **Article 257. General requirements for efficiency, safety and quality of medical products**

1. Medical products shall be designed and manufactured in such a manner that when using in conditions and for purposes corresponding to their use, defined by the manufacturer, and, where necessary, in consideration of know-how, experience, education and special training, clinical and physical state of a user, they would operate as per the use defined by the manufacturer, and would be safe for the user and third persons, provided that risk related to their use is acceptable in correlation with benefit for the user.

2. Medical products shall be designed, manufactured and packed in such a manner that their performance specifications and efficiency are not deteriorated during transportation and storage in accordance with instruction for use.

3. Medical products must be as efficient as it is provided for by the manufacturer, and be designed and manufactured in such a manner that under normal conditions of operation, they meet the purpose of use determined by the manufacturer.

4. Performance specifications and efficiency of a medical product shall not alter to the extent which poses a risk to life and health of users and third persons during operating life, determined by the manufacturer, provided that such medical product is exposed to impacts, which may arise under normal operational conditions, and technical maintenance is performed in accordance with instruction for use.

5. For each medical product, it is necessary to present information required for identification of such medical product and its manufacturer, country of origin, as well as information for user (professional or non-professional), relating to safety of such medical product, its functional properties and performance specifications. Such information shall be placed on medical product itself, on its package or in instruction for use.

#### **Article 258. Classification of safety and re-classification of safety of medical products depending on the degree of potential risk of use**

1. Medical products used in the Republic of Kazakhstan are divided into classes depending on the degree of potential risk of use and into types in accordance with the assortment of medical products of the Republic of Kazakhstan.

2. Rules for classification of medical products depending on the degree of potential risk of use are approved by the authorized body.

3. Class of medical products as per the degree of potential risk of use shall be approved upon state registration by the authorized body. Each medical product may only belong to one class.

4. Procedures for formation and maintenance of assortment of medical products of the Republic of Kazakhstan shall be defined by the authorized body.

5. The authorized body may enter amendments into classification based on detailed accounting of principles, occurrences, medical methods, underlying operation of medical products.

**Article 259. Suspension, prohibition or withdrawal from circulation or restricted use of pharmaceutical products and medical products**

1. The authorized body may suspend or prohibit the use, sale or production of pharmaceutical products and medical products, and take a decision to withdraw from circulation or to restrict use in the following cases:

- 1) non-compliance of pharmaceutical products and medical products with the requirements of the laws of the Republic of Kazakhstan in the field of public healthcare;
- 2) identification of adverse reactions of pharmaceutical products dangerous to human health, not specified in package leaflet, or increased frequency of identification of serious adverse reactions, specified in leaflet, or lower therapeutic efficacy (lack of therapeutic benefit), or available information on suspension and (or) its withdrawal from markets of other countries due to identification of adverse reactions with unfavourable "benefit-risk" relation;
- 3) identification of defects in design, operation, construction in the course of application of medical products, which affect safety of their application;
- 4) violation of approved process of production of pharmaceutical products and medical products, which affects safety, quality and efficiency of their application;
- 5) available data on harm to health of a patient or user due to application of pharmaceutical products and medical products;
- 6) receipt of data on inadequate scientific and technical level of production method and quality control, which lead to lower level of safety of application of pharmaceutical products and medical products;
- 7) application of the holder of a certificate of registration on suspension, on withdrawal of certificate of registration or withdrawal from circulation, or restriction of application of pharmaceutical products and medical products;
- 8) non-compliance of pharmaceutical products with the requirement of good pharmacy practices of the Republic of Kazakhstan and (or) Eurasian Economic Union, identified following pharmaceutical inspection;
- 9) non-performance of obligations on pharmacovigilance by a holder of certificate of registration for a pharmaceutical product or by a manufacturer of a medical product on monitoring of safety, quality and efficiency of medical products.

2. Rules for suspension, prohibition or withdrawal from circulation or restricted application of pharmaceutical products and medical products shall be approved by the authorized body.

**Article 260. Falsified, counterfeit pharmaceutical products and medical products**

1. It is prohibited to produce, import, store, use and sell falsified, counterfeit pharmaceutical products and medical products in the Republic of Kazakhstan.

2. Falsification of pharmaceutical products and medical products (presentation of false information on performance and (or) on source of origin) also includes accessories, parts and materials manufactured and designed for production of falsified products.

3. Prevention and fight against falsification of pharmaceutical products and medical products is administered by the authorized body in cooperation with concerned government bodies, organizations of manufacturers of pharmaceutical products and medical products, public healthcare entities and non-government organizations.

4. The authorized body implements international cooperation in the fight against falsified, counterfeit pharmaceutical products and medical products.

#### **Article 261. Pharmacovigilance and monitoring of safety, quality and efficiency of medical products**

1. The authorized body ensures operation of pharmacovigilance system and conducts monitoring of safety, quality and efficiency of medical products in the Republic of Kazakhstan.

2. State expert organization in the field of circulation of pharmaceutical products and medical products for the purposes of maintenance public health protection and improvement of safety of patients shall perform:

1) collection, analysis, assessment and verification of reports on adverse reactions of a pharmaceutical product, undesired events with a medical product received from entities of public healthcare and entities in the field of circulation of pharmaceutical products and medical products, consumers;

2) assessment of "benefit-risk" relation of pharmaceutical products and medical products on the basis of data of pharmacovigilance and monitoring of safety, quality and efficiency of medical products in the Republic of Kazakhstan, data, provided by holders of certificate of registration for pharmaceutical products, producers of medical products, data, received from other sources.

3. Procedures for conduction of pharmacovigilance and monitoring of safety, quality and efficiency of medical products shall be determined by the authorized body.

4. Pharmacovigilance and monitoring of safety, quality and efficiency of medical products shall be conducted by public healthcare entities, entities in the field of circulation of pharmaceutical products and medical products, as well as by holders of certificate of registration of pharmaceutical products and producers of medical products, organizations on service maintenance of medical products.

5. Public healthcare entities shall notify in written and in timely manner the authorized body of events of manifestation of adverse reactions, including those not specified in instruction for use of a pharmaceutical product, on patterns of interaction of a pharmaceutical

product with other pharmaceutical products, on overdose, drug dependence, abuse, on absence or lower efficiency of a pharmaceutical product and on adverse events of medical products.

Holder of a certificate of registration of a pharmaceutical product and manufacturer of a medical product shall in full present to the authorized body data on safety of a pharmaceutical product, and in timely manner notify the authorized body of events of manifestation of adverse reactions and (or) adverse events in application of a pharmaceutical product or medical product.

6. The authorized body shall take into account data of pharmacovigilance and monitoring of safety, quality and efficiency of medical products in other countries when taking decision on suspension, prohibition or withdrawal from circulation, or restricted use of pharmaceutical products and medical products in the Republic of Kazakhstan.

#### **Article 262. Information on pharmaceutical products and medical products**

Information on pharmaceutical products and medical products approved for application and use in the Republic of Kazakhstan, on pharmaceutical products, which have not passed state registration, not meeting the requirements of the laws of the Republic of Kazakhstan in the field of public healthcare, on withdrawal of decision on state registration, as well as on pharmaceutical products, which are dispensed on prescription of a physician, shall be communicated in special print media designed for medical and pharmaceutical personnel.

#### **Article 263. Kazakhstan National Drug Formulary**

1. Kazakhstan National Drug Formulary is developed based on pharmacotherapeutic and (or) anatomicotherapeutic classification of pharmaceutical products.

2. For generation of Kazakhstan National Drug Formulary, State Register of Pharmaceutical Products and Medical Products shall be used.

3. Pharmaceutical products shall be entered into Kazakhstan National Drug Formulary under international non-proprietary name of a pharmaceutical product with specification of each trade name of such pharmaceutical product, registered in the Republic of Kazakhstan.

4. Rules for generation of Kazakhstan National Drug Formulary shall be developed and approved by the authorized body.

#### **Article 264. Rational use of pharmaceutical products**

1. Rational use of pharmaceutical products is intended for improvement of quality of medical care and outcomes of treatment through development of formulary system.

2. Formulary system ensures optimal utilization of safe, efficient, economically accessible pharmaceutical products. Operation of the formulary system shall be maintained in accordance with the procedures determined by the authorized body.



3. Public healthcare organizations shall ensure rational utilization of pharmaceutical products, training of clinical pharmacologists, clinical pharmacists and regular advance training of specialists in the field of public healthcare on rational use of pharmaceutical products.

#### **Article 265. Ethics of promotion of pharmaceutical products and medical products**

1. Ethics of promotion of pharmaceutical products and medical products is activities carried out in the course of promotion of safe, quality and efficient pharmaceutical products and medical products from a developer and (or) producer of a pharmaceutical product or medical product prior to its use by consumer based on fair competition and liability of all parties concerned.

2. Ethics of promotion of pharmaceutical products and medical products shall be implemented in accordance with the procedures determined by the authorized body.

3. For the purposes of rational utilization of pharmaceutical products and medical products, public healthcare entities, members of professional associations, entities in the field of circulation of pharmaceutical products and medical products must comply with the following terms of ethics of promotion of pharmaceutical products and medical products:

1) promotion of pharmaceutical products and medical products at the market must ensure completeness and accuracy of information presented regarding safe, quality and efficient pharmaceutical products and medical products;

2) patients, pharmaceutical and medical personnel must receive necessary and available information on pharmaceutical products and side effects;

3) promotion of pharmaceutical products and medical products at the market must be objective, comply with ethical standards and be implemented in accordance with the requirements of the laws of the Republic of Kazakhstan in the field of public healthcare.

4. In medical organizations and organizations of education in the field of public healthcare, it is prohibited to promote pharmaceutical products and medical products by representatives of manufacturers of pharmaceutical products and medical products and (or) distributors, except for daily doctors' conferences, research-to-practice conferences and (or) special workshops.

Daily doctors' conference is a routine meeting of a medical organization aimed to review results of a day, discuss and examine clinical events, and notify staff of new achievements in medical science and clinical practice.

### **SECTION 6. PERSONNEL POLICY IN THE FIELD OF PUBLIC HEALTHCARE**

#### **Chapter 29. HUMAN RESOURCES IN THE FIELD OF PUBLIC HEALTHCARE**

##### **Article 266. National system of accounting of human resources in the field of public healthcare**

1. National system of accounting of human resources in the field of public healthcare (professional register) is a basis for registration, accounting, migration, outflow for the purposes of personal record-keeping, as well as continuous professional development of public healthcare personnel.

Procedures of accounting of human resources in the field of public healthcare (keeping of professional register) shall be defined by the authorized body.

2. On the basis of data of the professional register of public healthcare personnel, monitoring and forecasting of development of labour market and human resources, and planning of personnel training are implemented.

3. Persons, having certificates of specialist in the field of public healthcare are subject to mandatory registration in the National system of accounting of human resources in the field of public healthcare. Certificate of specialist in the field of public healthcare shall be valid in case of its registration in the National system of accounting of human resources in the field of public healthcare.

4. National coordinator on human resources in the field of public healthcare shall be defined by the authorized body.

#### **Article 267. Special aspects of sectoral system of qualifications in the field of public healthcare**

1. Sectoral system of qualifications in the field of public healthcare is a combination of mechanisms of legal and institutional regulation of demand for qualifications of public healthcare personnel on the part of the labour market and offer of qualifications on the part of the system of education in the field of public healthcare, including:

- 1) sectoral qualification framework in the field of public healthcare;
- 2) occupational standards in the field of public healthcare;
- 3) state compulsory standards of education in the field of public healthcare;
- 4) certification of specialists in the field of public healthcare;
- 5) system for continuous professional development of public healthcare personnel.

2. Occupational standards in the field of public healthcare shall be developed on medical and pharmaceutical specialties.

#### **Article 268. Principles for implementation of personnel policy in the field of public healthcare**

1. Implementation of personnel policy in the field of public healthcare is based on the following principles:

1) joint liability of the government and professional medical community, including professional medical associations, employers, medical and pharmaceutical personnel, for early and quality delivery of healthcare services;

2) regulation of human resources in the field of public healthcare for the purposes of satisfaction of real needs of the sector;

3) control and assistance in maintenance of training (preparation) of human resources in the field of public healthcare;

4) rational and efficient implementation of capacities of human resources in the field of public healthcare;

5) strengthening the status of administrative human resources in the field of public healthcare;

6) training of human resources in the field of public healthcare in consideration of current and further needs of the public healthcare system;

7) continuous improvement of programs of training of human resources in the field of public healthcare;

8) independent evaluation of expertise, competences, occupational training of human resources in the field of public healthcare;

9) development of professional medical associations;

10) social security for medical personnel;

11) availability of necessary human resources in the field of public healthcare;

12) generation of proper competences and skills of personnel;

13) continuous professional development (life-long learning);

14) improvement of productivity of human resources in the field of public healthcare;

15) social recognition.

2. Personnel policy in the field of public healthcare is formed:

1) at the republic level - by an authorized body, approving national policy of human resources management in the field of public healthcare;

2) at the regional level - by local public healthcare authorities of regions, cities of republican status and the capital city, approving regional policy of human resource management in the field of public healthcare;

3) at the level of public healthcare organizations - by public healthcare organizations, implementing corporate personnel policy.

3. Planning of training of medical and pharmaceutical personnel is implemented by the authorized body, central executive bodies and other central government bodies, having military-medical (medical) subdivisions, as well as local public healthcare authorities of regions, cities of republican status and the capital city within their competencies in consideration of needs of the sector.

#### **Article 269. Continuous occupational development of public healthcare personnel**

1. Continuous occupational development of medical and pharmaceutical personnel is designed for improvement of professional expertise and skills, acquisition of additional competences, considering needs of specialists, for the purposes of improvement of safety of medical services.

2. Outcomes of continuous occupational development of medical and pharmaceutical personnel shall be verified on the basis of accounting data of the professional register on additional and informal education, other activities on occupational development, level of competency, approved work experience.

3. Outcomes of continuous occupational development of medical and pharmaceutical personnel shall be verified in view of the requirements to the level of qualification, established by occupational standard and qualification criteria to professional duties of public healthcare personnel.

4. Professional medical associations shall participate in development of occupational standards and educational programs for additional and informal education.

## **Chapter 30. STATUS OF MEDICAL AND PHARMACEUTICAL PERSONNEL**

### **Article 270. Status of medical and pharmaceutical workers and their rights**

1. Medical and pharmaceutical personnel shall have a right for fundamental guarantees, provided for by the laws of the Republic of Kazakhstan and other regulatory legal acts, including for:

1) creation of proper conditions for personnel for performance of employment duties, including provision with necessary medical products in accordance with the procedures, established by the laws of the Republic of Kazakhstan;

2) advance training or change of professional qualification at the expense of employer or out of public funds, provided for such purposes by the laws of the Republic of Kazakhstan, when it is impossible to perform employment duties for medical reasons and in case of dismissal of personnel due to reduction in force or personnel, due to liquidation of an organization;

3) labour remuneration conforming to qualification level;

4) work motivation in accordance with level of qualification, specificity and complexity of work, scope and quality of labour, as well as with certain performance outcomes;

5) establishment of professional associations and participation therein;

6) insurance of professional liability of medical workers in case of harm to life and (or) health of a patient when providing medical care;

7) compensation for damage to life and health during performance of official duties, in accordance with the laws of the Republic of Kazakhstan;

8) engagement in private medical practice and pharmaceutical activities upon availability of authorization documents for medical and pharmaceutical activities;

9) unrestricted and free-of-charge use of communication means, owned by individuals and legal entities in case of transportation of a patient to the nearest medical organization to deliver urgent medical aid;

10) compensation for transportation expenses relating to transit.

2. Workers with technical and professional, post-secondary degree, higher, post-graduate medical degree, confirmed by a certificate of specialist in the field of public healthcare have a right to engage in medical activities.

3. Resident physicians within the period of their studies have a right to work at medical organizations in accordance with certificate of specialist in the field of public healthcare under the supervision of a mentor.

4. Persons, who earned medical degree abroad, shall be admitted to medical or pharmaceutical activities after recognition of documents of education, a positive result of the evaluation of professional qualifications at an organization, with issue of a certificate of specialist in the field of healthcare.

Evaluation of professional qualifications of persons, who earned medical degree abroad, shall be conducted in accordance with the rules for evaluation of professional qualification of graduates on programs of medical education.

5. Medical incident is an event relating to delivery of medical services in accordance with standards of an organization delivering medical services and using technology, equipment and tools, associated with deviation from proper functioning of an organism which may cause damage to life and health of a patient, or also lead to death of a patient, except for cases, provided for by administrative and criminal laws of the Republic of Kazakhstan.

Analysis of a medical incident shall be carried out through internal audit of a medical organization, as well as by local public healthcare authorities of regions, cities of republican status and the capital city, government bodies, exercising state control in the field of delivery of medical service (aid), public sanitary and epidemiological welfare, circulation of pharmaceutical materials and medical materials, the authorized body.

**Footnote. Article 270 as amended by the Law of the Republic of Kazakhstan dated 08.01.2021 № 410-VI (shall be enforced upon expiration of ten calendar days after the date of its first official publication); dated 03.01.2022 № 101-VII (shall be enforced from 01.01.2023 ).**

## **Article 271. Obligations of medical and pharmaceutical personnel**

1. Medical and pharmaceutical personnel shall carry out activities in accordance with the laws of the Republic of Kazakhstan and, being guided by the principles of medical ethics and deontology, shall:

1) facilitate disease prevention, health promotion, promotion of healthy lifestyle among people of the Republic of Kazakhstan;

2) deliver medical services in accordance with own qualification, official and job duties;

3) refer, where necessary, for advice to specialists of other profile or higher qualification;

4) keep secret of medical worker, not disclose details on diseases, intimate and family life of a patient;

5) improve own professional level on a continuous basis;

6) be registered in the National system of accounting of human resources in the field of public healthcare;

7) in medication, prescribe pharmaceutical materials within own competence where there are respective medical indications under international non-proprietary name, except for cases of idiosyncrasy of a patient.

2. Medical and pharmaceutical personnel, heads of medical organizations shall not have a right to:

1) participate in advertising of pharmaceutical materials and medical materials;

2) recommend certain facilities of retail trade of pharmaceutical products and medical products to patients for the purposes of self-interest in receiving remuneration for own services;

3) promote pharmaceutical products and medical products with participation of representatives of manufacturers of pharmaceutical products and medical products and (or) distributors, except for daily doctors' conferences, research-to-practice conferences and (or) special workshops.

#### **Article 272. Social guarantees Social protection for medical and pharmaceutical personnel**

1. Medical personnel of state medical organizations, working in rural areas and in settlements, cities of district status, the following forms of social assistance shall be provided for:

1) mandatory provision of housing upon decision of local executive bodies, including service housing, in accordance with the laws of the Republic of Kazakhstan;

2) mandatory allowance payment in accordance with procedures established by a local executive body;

3) provision of social support on compensation for utility expenses and other benefits upon decision of local executive bodies;

4) other measures.

2. Medical and pharmaceutical personnel of state medical organizations have a priority right after vulnerable social groups to receive forms of social assistance, additional benefits and incentive payments at the expense of local budgets.

3. Local executive bodies in order to promote prestige of medical personnel and to maintain improvement of its personal and professional growth shall assign status "Best in Profession" with provision of incentive payments at the expense of local budgets.

4. Interference in professional activities of medical and pharmaceutical personnel on the part of government bodies and officials, as well as citizens of the Republic of Kazakhstan is prohibited, except for cases provided for by this Code.

5. In carrying out professional activities by a medical or pharmaceutical worker, the following is not allowed:

1) involvement in types of works not related to professional duties, except for cases, provided for by the laws of the Republic of Kazakhstan;

2) demand of reports or information, not provided for by the laws of the Republic of Kazakhstan;

3) imposition of obligations on procurement of goods (works) and services, not provided for by the laws of the Republic of Kazakhstan.

### **Article 273. Secrecy of medical worker**

1. Personal medical data, information on event of seeking medical advice, state of health of a person, diagnosis of his disease and other details, obtained during examination and (or) treatment constitute secrecy of medical worker.

2. It is not allowed to disclose details constituting secrecy of medical worker, by persons, to whom they become known during training, performance of professional duties, official and other obligations, except for cases specified in paragraphs 3 and 4 of this article.

3. With informed consent of a patient or his legal representative, it is allowed to convey information, constituting secrecy of medical worker, for conduction of research activities, use of such information in educational process.

4. Provision of information, constituting secrecy of medical worker, without consent of a person is allowed in following cases:

1) for the purposes of examination and treatment of a person, incapable due to his state to express own will, in case of absence of a legal representative;

2) under the threat of disease distribution, constituting a danger to the public, including in donation of blood, its components, transplantation of organs (part of an organ) and (or) tissues (part of tissue);

3) upon request from bodies of inquiry and preliminary investigation, prosecutor, attorney and (or) court due to conduction of investigation or judicial proceedings;

4) in delivery of medical services to a minor child or incompetent person to notify his legal representative;

5) if there are grounds to suppose that damage to health of a citizen of the Republic of Kazakhstan is caused as a result of unlawful acts;

6) in case of disclosure of mental deviations and propensity towards sexual violence of a person;

7) in exercising state control of quality of delivery of medical services (aid), monitoring of contractual obligations on quality and scope of medical services;

8) when conducting inspections by the prosecutor's office in accordance with the procedure established by the Constitutional Law of the Republic of Kazakhstan "On the Prosecutor's Office";

9) upon request of special state bodies for the purposes of solution of tasks of counterintelligence activities.

5. The following shall not be considered as disclosure of secrecy of medical worker:

1) transmission for storage of a backup copy of electronic information resource to an integrated platform for standby storage of electronic information resources in accordance with the procedures and within the terms, established by an authorized body in the field of maintenance of information security, except for cases, when such electronic information resources contain information, related to intelligence, counterintelligence activities and guard activities on maintenance of safety of protected persons and facilities, transmission whereof is implemented in accordance with the laws of the Republic of Kazakhstan on state secrets;

2) exchange of information using information and communication technology for the purposes of delivery of medical services and to maintenance of operation of law enforcement and special state bodies.

6. It is not allowed to connect electronic information resources containing personal medical data of individuals to telecommunications networks linking them with other databases without the consent of individuals when using personal medical data related to their private life, except in cases related to blood donation and its components, organs (parts of an organ) and (or) tissues (parts of tissue), as well as requests from law enforcement and special state bodies to provide information in the form of an electronic document constituting a medical secret, about the registered persons suffering from or who have had tuberculosis, with mental and behavioral disorders (diseases) associated with the use of psychoactive substances.

7. Cases, when data on health of a patient become available due to reasons beyond the control of a medical worker, shall not be considered as violation of secrecy of medical worker

**Footnote. Article 273 as amended by the Law of the Republic of Kazakhstan dated 05.11.2022 № 157-VII (shall be enforced ten calendar days after the date of its first official publication); dated 23.12.2023 № 51-VIII (effective ten calendar days after the date of its first official publication).**

#### **Article 274. Code of honour of medical and pharmaceutical personnel of the Republic of Kazakhstan**

1. Code of Honour of medical and pharmaceutical personnel of the Republic of Kazakhstan (hereinafter referred to as Code of Honour) establishes moral and ethical liability of medical and pharmaceutical workers of the Republic of Kazakhstan for their activities before the public.

2. Code of Honour shall be developed and approved by the authorized body.

#### **SECTION 7. FINAL PROVISIONS**

#### **Article 275. Liability for violation of the laws of the Republic of Kazakhstan in the field of public healthcare**



Violation of the laws of the Republic of Kazakhstan in the field of public healthcare creates liability, established by the laws of the Republic of Kazakhstan.

#### **Article 276. Procedures for enforcement of this Code**

1. This Code shall enter into force upon expiration of ten calendar days after its first official publication, except for:

1) article 39, subparagraph 1) paragraph 10 article 55, which shall enter into force on January 1, 2021;

2) part two paragraph 2 article 231 and part two paragraph 3 article 233, which shall enter into force for organizations producing pharmaceutical products, pharmacy depots on January 1, 2021;

3) paragraph 7 article 240, which shall enter into force on June 1, 2021;

4) subparagraph 16) paragraph 2 article 110, subparagraphs 2), 3) paragraph 1, subparagraphs 2), 3) paragraph 4, paragraphs 7 and 8 article 27, which shall enter into force on July 1, 2021;

5) subparagraph 2) paragraph 10 article 55, which shall enter into force on January 1, 2022;

6) part one paragraph 3 article 233, which shall enter into force for chemist's shops on January 1, 2023;

7) Excluded by the Law of the Republic of Kazakhstan dated 27.06.2022 № 129-VII ( shall be enforced ten calendar days after the date of its first official publication).

2. Excluded by the Law of the Republic of Kazakhstan dated 27.06.2022 № 129-VII ( shall be enforced ten calendar days after the date of its first official publication).

3. Excluded by the Law of the Republic of Kazakhstan dated 27.06.2022 № 129-VII ( shall be enforced ten calendar days after the date of its first official publication)..

4. Suspend prior to enforcement of subparagraph 1) paragraph 22 article 1 of the Law of the Republic of Kazakhstan dated May 13, 2020 "On introduction of amendments and additions to some legal acts of the Republic of Kazakhstan on issues of regulation of migration processes" the force of title of article 83 in title list of content, title, paragraphs 1 and 3 article 83, paragraph 2 article 160, paragraph 1 article 162 and part one paragraph 1 article 196 of this Code, by establishing that within the period of suspension, such norms shall be in force as follows:

1) title of article 83 in list of content:

"Article 83. Rights and obligations of oralmans (repatriates), foreigners, persons without citizenship and other persons";

2) title of article, subparagraphs 1 and 3 article 83:

"Article 83. Rights and obligations of oralmans (repatriates), foreigners, persons without citizenships and other persons

1. Oralman (repatriates), refugees, as well as foreigners and persons without citizenship, permanently residing in the Republic of Kazakhstan, have a right to receive statutory free medical assistance on an equal basis with citizens of the Republic of Kazakhstan”;

“3. Oralman (repatriates), refugees and persons, seeking refuge, foreigners and persons without citizenship, residing in the Republic of Kazakhstan, bear the same obligations in the field of public healthcare as citizens of the Republic of Kazakhstan;

3) paragraph 2 article 160:

“2. HIV-infected citizens of the Republic of Kazakhstan, oralman (repatriates), foreigners, persons without citizenship, refugees, permanently residing in the Republic of Kazakhstan, and children born of HIV-infected mothers with unidentified diagnosis, shall be subject to case follow-up and provision with pharmaceutical products within statutory free medical assistance”;

4) paragraph 1 article 162:

“1. Citizens of the Republic of Kazakhstan, oralman (repatriates), foreigners, persons without citizenship, refugees and persons, seeking refuge, permanently or temporarily residing in the Republic of Kazakhstan, have a right for voluntary anonymous and (or) private medical examination and advice on issues of HIV-infection within statutory free medical assistance in state organizations of public healthcare, carrying out activities in the field of HIV prevention, in accordance with the procedures, determined by the authorized body”;

5) part one paragraph 1 article 196:

“1. Statutory free medical assistance shall be provided to citizens of the Republic of Kazakhstan, oralman (repatriates), refugees, foreigners and persons without citizenship, permanently residing in the Republic of Kazakhstan, at the expense of budgetary funds, includes prophylactic, diagnostic and therapeutic medical services, having best proven efficiency, as well as pharmacological support”.

5. The following shall be deemed to have lost force:

1) Code of the Republic of Kazakhstan dated September 18, 2009 “On People’s Health and Healthcare System” (Bulletin of the Parliament of the Republic of Kazakhstan, 2009, № 20-21, article 89; 2010, № 5, article 23; № 7, article 32; № 15, article 71; № 24, articles 149, 152; 2011, № 1, articles 2, 3; № 2, article 21; № 11, article 102; № 12, article 111; № 17, article 136; № 21, article 161; 2012, № 1, article 5; № 3, article 26; № 4, article 32; № 8, article 64; № 12, article 83; № 14, articles 92, 95; № 15, article 97; № 21-22, article 124; 2013, № 1, article 3; № 5-6, article 30; № 7, article 36; № 9, article 51; № 12, article 57; № 13, article 62; № 14, articles 72, 75; № 16, article 83; 2014, № 1, article 4; № 7, article 37; № 10, article 52; № 11, article 65; № 14, articles 84, 86; № 16, article 90; № 19-I, 19-II, article 96; № 21, article 122; № 23, article 143; 2015, № 1, article 2; № 7, article 33; № 10, article 50; № 19-II, article 102; № 20-IV, article 113; № 20-VII, article 115; № 22-I, article 143; № 22-V, article 156; № 23-II, article 170; 2016, № 6, article 45; № 8-II, articles 67, 70; № 23, article 119; 2017, № 1-2, article 3; № 4, article 7; № 9, article 22; № 13, article 45; № 22-III,

article 109; № 23-III, article 111; № 24, article 115; 2018, № 10, article 32; № 14, article 42; № 15, article 47; № 19, article 62; № 23, article 91; № 24, articles 93, 94; 2019, № 7, article 36; № 8, article 46; № 21-22, article 90; № 23, article 106; Law of the Republic of Kazakhstan dated May 4, 2020 “On introduction of amendments and additions to some legal acts of the Republic of Kazakhstan on issues of labour”, published in newspapers “Yegemen Qazaqstan” and “Kazakhstanskaya Pravda” on May 5, 2020; Law of the Republic of Kazakhstan dated May 13, 2020 “On introduction of amendments and additions to some legal acts of the Republic of Kazakhstan on issues of regulation of migration processes”, published in newspapers “Yegemen Qazaqstan” and “Kazakhstanskaya Pravda” on May 14, 2020; Law of the Republic of Kazakhstan dated May 25, 2020 “On introduction of amendments and additions to some legal acts of the Republic of Kazakhstan on issues of mobilization preparation and mobilization”, published in newspapers “Yegemen Qazaqstan” and “Kazakhstanskaya Pravda” on May 26, 2020);

2) Law of the Republic of Kazakhstan dated April 7, 1995 “On compulsory treatment of patients with alcohol, drug and inhalant dependence” (Bulletin of the Supreme Soviet of the Republic of Kazakhstan, 1995, № 3-4, article 32; Bulletin of the Parliament of the Republic of Kazakhstan, 2004, № 23, article 142; 2010, № 24, article 152; 2012, № 8, article 64; 2013, № 13, article 62; 2014, № 19-I, 19-II, article 96; 2018, № 24, article 93);

3) Law of the Republic of Kazakhstan dated October 14, 2003 “On Prevention of Iodine Deficiency Disorders” (Bulletin of the Parliament of the Republic of Kazakhstan, 2003, № 19-20, article 149; 2006, № 1, article 5; 2007, № 4, article 95; 2011, № 11, article 102; 2012, № 14, article 92; 2013, № 14, article 75; 2014, № 1, article 4; № 23, article 143; 2018, № 24, article 93).

**Footnote. Article 276 as amended by the Law of the Republic of Kazakhstan dated 27.06.2022 № 129-VII (shall be enforced ten calendar days after the date of its first official publication).**

*The President of the Republic of Kazakhstan*

*K. TOKAYEV*