The Concept of the draft Code of the Republic of Kazakhstan "On public health and healthcare system"

Notice

This is an unofficial English translation of The Concept of the draft Code of the Republic of Kazakhstan "On public health and healthcare system" prepared by GRATA International Law Firm. Please see the Russian version here→

1. Title of the draft law

The Code of the Republic of Kazakhstan "On public health and healthcare system" (hereinafter – "**the draft Code**").

2. The rationale for the development of the draft law

The head of state in his Message to the people of Kazakhstan "Kazakhstan - 2030 Prosperity, Security, and Improving the Welfare of All Kazakhstan People" set goals to preserve the health of our population throughout the life of citizens.

In addition, in his next Message to the people of Kazakhstan "Kazakhstan's Way - 2050: A Single Goal, Common Interests, Common Future", the President of the country defined health as a key factor in the development of the state, and also outlined the basic principle of developing a healthcare system, expressed in the joint responsibility of the state, employers and the population for the health of citizens. The country has a new task to become one of the 30 most competitive countries in the world, which also means a high level of quality of healthcare.

The current Code of the Republic of Kazakhstan dated September 18, 2009, "On public health and healthcare system" laid down the initial stages of the development of the healthcare system for Kazakhstan to enter the 50 most competitive countries in the world.

Realization of the task to become one of the 30 most competitive countries in the world requires accelerated healthcare system development, which fundamentally changes the current healthcare system understanding, including the legislation of the Republic of Kazakhstan in the healthcare field.

Achieving this goal requires the system to quickly group its efforts to build a new, long-term healthcare model based on the best examples of our own and world experience, which will ensure the availability and quality of medical services, while maintaining financial stability in the event of any fluctuations in the global and domestic economies. Also, the need to develop a new version of the draft Code is due to the rapid emergence of new technologies in medicine and the growth of expectations among the population regarding access to health services based on the latest healthcare achievements.
At the same time, the development of a new version of the draft Code is due to the need to implement the Message of the President of the Republic of Kazakhstan dated January 10, 2018, "New Development Opportunities in the Conditions of the Fourth Industrial Revolution" in order to comply with global trends and global challenges of domestic health care.
To become one of the 30 most competitive countries in the world, it is necessary to go through the path of deep modernization and the achievement of fundamental development indicators, which are now demonstrated by the member states of the Organization for Economic Cooperation and Development (hereinafter – "**the OECD**").

In turn, for all the difference in funding sources and management systems, the main distinguishing features of the OECD countries' health models from our system are the following.

1. The priority of health and the development of public health Concern and increased attention to noncommunicable diseases (hereinafter – "**the NCDs**") is one of the characteristic features of the health care of all developed countries, which is due, first of all, to the steady growth trend in the incidence rate, which has reached quite high rates in the foreseeable future will increase.

According to the World Health Organization (hereinafter – "**the WHO**"), human health depends on the health system only by 10% and 50% on the lifestyle that is formed under the influence of the human environment, the right to choose, quality of life and the accessibility of health promotion opportunities. Prevention offers the most cost-effective long-term strategy to combat NCDs. Solidarity in health promotion issues, the active participation of civil society in solving health problems are one of the main distinguishing features of the health systems of OECD countries.

In Kazakhstan, the issues of preventive work, increasing efforts of intersectoral cooperation on NCD problems, the development and implementation of special programs for the management of chronic diseases aimed at improving the medical services quality at all levels of healthcare organizations are at the initial stage.

*2. The preferential development of primary health care (hereinafter - "**the PHC**") in the total amount of allocated funds for health care*

International experience proves that the necessary coverage of the population and the effective provision of PHC services is achieved with the funding of outpatient services at the level of at least 40% of health care costs. Kazakhstan is approaching this ratio of costs for primary care.

Despite the increasing role of primary health care in the country, significant shifts in the improvement of primary health care delivery have not yet occurred. In terms of its technical and personnel equipment, this sector could not become a central link in the healthcare system and ensure a rational distribution of treatment stages at the outpatient and inpatient levels.

The presence of a strong PHC allows the OECD countries to keep up to 80% of patients at their level, thus becoming the main coordinator of the entire system, while in our system the main operating structure continues to be the stationary sector.

3. Maximum public access to essential medicines

The role of medicine provision is essential in maintaining and maintaining health, which is why in OECD countries the issue of quality and safety of medicines has been raised to the level of national biological safety.

In OECD countries, an average of 80% of the total funding for medicine provision goes to providing patients with medicines on an outpatient basis.

In the structure of state expenditure on medicines, the share of outpatient medicine provision in Kazakhstan is only 45%. Insufficient medicine provision at the outpatient level inhibits the development of primary health care and stimulates excessive hospitalization in a hospital.

At the same time, in OECD countries, the share of drug costs in the total cost of hospitals does not exceed 20%.

Currently, in Kazakhstan this indicator reaches 50%.

The main reasons are the lack of methods knowledge for assessing the proven medical organizations effectiveness, the inclusion facts of medicines with low economic and clinical effectiveness in the drug formulations, leading to the formation of a medicines list that do not reflect the real need. As a result, medical organizations have a deficit in some medicines types, and a surplus in others.

4. High labour motivation and professionalism of the medical staff

In Kazakhstan, the average nominal monthly doctor's salary is about 125 000 tenge, which is almost 16 times lower than in OECD countries (about 2 000 000 tenge). This determines the prestige of the profession and the weak medical workers labour motivation in Kazakhstan.

It should also be noted the weak dependence of wages on its intensity and outcome, as well as on the qualifications of workers.

The professional level of the nursing staff is still poor outdated teaching methods, low prestige of the profession and unsatisfactory wages are applied.

The level of motivation of medical organizations and staff to intensify labour, reduce the cost of services, and increase their quality is still insufficient. Differentiated wage is made by vacant rates and a continuing shortage of specialists, especially in rural areas.

The issue of training managers remains at a low level, which is one of the main factors of service inefficiency. Appointments to the posts of heads of medical organizations, industry management bodies occur without considering the qualifications of candidates and their ability to manage the system. Almost 50% of field managers do not comply with established qualification requirements.

5. Priority medical science

In most of the OECD countries, the share of domestic research and development costs in total GDP is about 3%. In Kazakhstan, despite the growth in funding for research and development (hereinafter – "**the R&D**") by 5 times since 2000, the share of domestic costs amounted to 0.26% of the Republic's GDP.

It is also worth noting that in developed countries, private sector spending on research (60-70%) exceeds government spending. In Kazakhstan, the inverse structure still prevails with the predominance of the role of the public sector in financing R&D.

6. High level and joint principle of health financing

The OECD countries average 8% of total health spending. To ensure the efficient functioning of the health care system, WHO recommends allocating as little as 6-8% of GDP with budget financing in developed countries and at least 5% of GDP in developing countries. The share of expenditures of Kazakhstan, as mentioned above, is only about 3%.

7. Low private health spending

In the OECD countries, the share of private spending on medical services is 19.6%; EU - 16.3%. Despite the growing funding and introduction of advanced methods of payment for medical services, in 2014 in Kazakhstan this indicator amounted to 35.4% of total health care spending. The level of population spending on medical services in excess of 20%, according to WHO, is a sign of financial instability of the health system and a high risk for the population.

The preservation of a significant amount of private expenses in the presence of the guaranteed volume of free medical care indicates a shortage of funds allocated to the system.

The lack of funding and the costs of new methods of payment for medical services led to the "overflow" of resources and the most qualified staff from primary care (PHC) to hospitals, and in hospitals - mainly to departments providing high-tech medical services (hereinafter – "**the HTMS**").

8. Developed information system

The global trend in healthcare development is closely related to the development of IT technologies. The OECD countries are in the process of introducing new communication technologies that may significantly simplify the relationship between doctor and patient. The development of smart medicine is becoming the main trend in the development of the industry.

In Kazakhstan, despite significant progress in introducing modern information technologies into the industry, creating a number of portals, improving the provision of computer equipment, developed and implemented web applications are aimed only at solving certain issues of financing and managing the

healthcare system. Existing databases are fragmented, which impedes the integration and continuity of different levels and health services.

Given the differences between the health care system of our country and the OECD countries, this draft Code is intended to make the foundations for accelerated development of the industry to ensure that the level of health care complies with the level of the OECD countries, for which the economy of the republic has all the necessary resources.

Based on this, the draft Code aims to manage public health based on genomic medicine, which covers the entire human life cycle. Thus, further medical care will be focused on the prevention and solution of health problems at each stage of human development. As part of the development of medical education in the Republic of Kazakhstan, the phased implementation of licensing of medical activities will be considered. Improving the accessibility and effectiveness of medical care through the integration of information systems, the use of mobile digital applications, the introduction of electronic health passports, the transition to paperless medicine, including electronic personal accounts of patients.

With the growth of offers of new treatment methods and technologies, the expectations of the population regarding access to health services are also growing. To justify the expectations of the population, it is necessary to develop scientific activities, including the clinical research market and improve the quality of bioethical examination, the effectiveness of medical care, the introduction of clinical treatment and diagnosis protocols.

In this way, the new version of the draft Code will be aimed at strengthening the health of the nation, consolidating and developing the achieved successes and solving existing problems in the field of health and the healthcare system, filling in the gaps in the current legislation in the field of healthcare, and will also become the basis for the planned and progressive development of the industry until the year 2050.

It is proposed to conceptually review the following institutional sections of health legislation:

1. healthcare system and organization of medical care;
2. medical activities;
3. pharmaceutical activities and circulation of medicines, medical devices and medical equipment;
4. protecting the health of citizens;
5. activities in the field of sanitary and epidemiological welfare of the population and the protection of public health;
6. educational and scientific activities in the field of health;
7. legal status, social protection of medical and pharmaceutical workers.

In particular, it is proposed to reflect in the new version of the draft Code the following main areas:

I. Development of public health

According to the World Health Organization (WHO), human health depends on the healthcare system only by 10%, and the fact that the individual’s state of health is more dependent on his lifestyle, which is formed under the influence of the ever-increasing power of the human information environment, the right to choose the level of social status and the availability of opportunities for the formation of a certain lifestyle.

This year, in the Message of the President to the people of Kazakhstan, the main focus was on ensuring that modern healthcare is more focused on disease prevention, rather than on expensive inpatient treatment.

As part of the public health creation, its activities will be closely integrated with the primary level of medical care, relevant research organizations and programs. This will create the basis for the development of an integrated model of medical care organization.

International experience shows us reasonable economic arguments for urgent measures in the field of public health, especially for the prevention of noncommunicable diseases, which make a significant contribution not only to improving public health, but also to developing the country's economy.

Over the past 5 years, Kazakhstan has seen a growth trend in the burden of major noncommunicable diseases, such as circulatory system diseases by 5.4%, cancer by 2.1%, diabetes by 20%, and respiratory diseases by 10%. These chronic diseases are the leading causes of deaths worldwide. In recent years, mortality from them is higher than from infectious and parasitic diseases. In Kazakhstan, 67% of deaths are also attributable to chronic noncommunicable diseases.

Chronic noncommunicable diseases are the main causes of preventable morbidity and disability in the world. This challenge also affects the health of citizens of Kazakhstan and is associated with such key factors as the widespread occurrence of behavioural risk factors and a difficult demographic situation.

An analysis of the causes of mortality over the past 15 years has shown that further improvement in health indicators is possible only in conditions of the development of public health and the establishment of a health cult in society.

Gaps with OECD countries in health indicators need to be bridged.

There is also a significant negative impact on the health of the population of the main determinants: environmental factors (water, ecology), behavioural factors (unhealthy diet, low physical activity, bad habits), unsafe habitat (high injuries).

One of the global challenges will be active population migration and the outbreak of infections that are not characteristic of certain regions, as well as the emergence of new, previously unknown infections (Ebola, highly pathogenic influenza, coronavirus infection, etc.), the consequences of which can be avoided or minimized, thanks to the introduction International Health Regulations (hereinafter – "**the IHR (2005)**"). Kazakhstan is one of the 196 participating countries where IHR are introduced and should be applied.

In this situation, within the framework of the new version of the draft Code, the efforts of all social partners will be mobilized: the state, employers and citizens themselves to mitigate these challenges and build a highly effective and financially sustainable health system.

Intersectoral collaboration will be aimed at reducing the risk factors for diseases and close cooperation with international associations and organizations (WHO, UN, UNICEF, including with the aim of promoting and secondmentation Kazakhstan's specialists there).

The roles and functions of the National and Regional Coordination Councils, which are a key body in ensuring interagency cooperation, will be strengthened and legislated.

The Code will strengthen the role of the Ministry of Health, which allows for interagency coordination, in terms of implementing state policy in the implementation of the International Health Regulations, interagency coordination of measures to protect the health of citizens, as well as sanitary protection of the territory of the Republic of Kazakhstan.

The Code will also reflect measures to prevent socially significant diseases that pose a danger to others, such as HIV, tuberculosis, mental illness and other diseases.

The level of environmental pollution, unsatisfactory sanitary condition of cities and settlements, their improvement, insufficient measures to protect the health of working citizens, the solution of which is possible only at the intersectoral level, remains high.

In recent years, socially dependent and professionally determined health problems have progressed (disadaptive syndromes, fatigue and overwork, stressful diseases).

Achieving the goal of public health is impossible without intersectoral collaboration.

In this regard, the new version of the Code will define the tasks and responsibilities of each sector of the economy in solving public health issues.

The key problem for all areas of health protection is the formation of a health culture, increasing the prestige of health, self-awareness of the value of health as a factor of vitality, active longevity.

International experience attests to the responsibility of every citizen for the health of loved ones and those around him. For the formation of which it is necessary to train all citizens of the country, starting from school age, in the skills of first aid and the use of defibrillators.

It is necessary to provide by law:

- training all citizens of the country, starting from school age, in the skills of first aid;
- mandatory placement in public places of the necessary medical equipment to provide emergency cardioreanimation of first aid (defibrillators) as part of the social responsibility of business;
- the creation of medical centres in crowded places;
- mandatory first-aid skills for employees of community centres (entertainment centres, supermarkets, train stations, airports, subways, etc.);
- creation of a first-aid system by paramedics (emergency service personnel, law enforcement agencies, drivers, etc.).

The competence of the authorized body in the field of health in the development of requirements for the training of paramedics and the determination of the volumes and forms of first aid will be legislated.

Ensuring a healthy lifestyle and promoting well-being for all at any age is one of the goals of the Sustainable Development Concept until 2030, adopted at the UN Summit in 2015.

Based on WHO recommendations, approaches to the prevention of noncommunicable diseases are changing.

To ensure universal access to a balanced, healthy diet, reduce the burden of nutritionally-dependent noncommunicable diseases, overweight and obesity, the use of complex integrated measures aimed at the prevention of behavioural risk factors is required.

Suppressing or preventing unhealthy behaviour requires additional systemic health initiatives.

These include: a ban on advertising of alcohol or tobacco products, fast food, laws in support of the ban on smoking in public places, tax legislation that supports the improvement of food culture and food labelling.

The current legislative acts of the Republic of Kazakhstan prohibit the advertising of tobacco and tobacco products on external media or in the media, but do not affect the display of tobacco products in places of trade. According to the WHO Framework Convention on Tobacco Control, which Kazakhstan ratified in 2006, a complete ban is required on all forms of tobacco advertising, including on-site distribution. In this connection, it is necessary to bring existing legislation into line with the requirements of the WHO framework convention on tobacco control.

For example, OECD countries that use the most stringent and comprehensive set of anti-tobacco policies have been found to be more successful in lowering their smoking rates, while the percentage of smokers is reduced by 15% per year compared to countries with a less comprehensive tobacco strategy.

The low level of development of a culture of health among the population and the consumer attitude to health that remains in society, the lack of personal responsibility in terms of maintaining and strengthening it, and low hygiene skills, require strengthening awareness-raising and educational work among the population, as well as with respect to the individual, which also will be reflected in the Code.

This will be ensured by introducing into the Code the rights and duties of citizens, including information on the state of health and factors affecting health, the introduction of standards to strengthen the citizen's joint responsibility for their health in cases of refusal to participate and the implementation of preventive measures aimed at maintaining and strengthening health (vaccinations, preventive medical examination, screenings, adherence to the prescribed treatment regimen, self-monitoring of the disease, etc.), fulfilling

doctor's appointments, calling an ambulance, in disease management programs that subsequently lead to the development or progression and complications of diseases.

Measures aimed at creating a culture of a healthy lifestyle and involving the patient in maintaining and strengthening their own health will be provided.

In matters of effective strengthening of the health of citizens, the role of non-governmental organizations (NGOs), the media and the business community is growing, which will also be reflected in the Code.

There is a need for an employer to form an attitude towards the health of the employee as an economic mechanism for increasing the productivity and quality of work. The legislation will provide for the creation of favourable economic conditions for the development and implementation of a program to promote health and disease prevention among workers, create healthy jobs, as well as referral of workers to mandatory annual medical examinations and screening examinations.

Measures to reduce the cost of treatment and liability for violation of health standards should include:

- standards for the professional health of the employee (first of all, for professions with especially harmful conditions, for dangerous professions);

- standards, rules for working conditions, means of work, environment, governing the relationship of the employee with employers;

- legal interactions of the employer for any type of property and the employee in case of loss of health, injury, illness, including environmentally caused;

- selection of people working in harmful and dangerous professions, the normative level of their provision with technical means of protection, life support, and salvation.

In accordance with that, the employer and the employee will be equally responsible for health, while the employer will be more responsible for public health, and the employee will be more responsible for individual health.

It is also necessary to legislatively introduce the concept of "environmentally related diseases".

It is necessary to legislatively provide for the creation of favourable economic conditions for the development and implementation of a program to promote health and disease prevention among workers, create healthy jobs, as well as stimulate and encourage investors who invest their funds in improving social conditions and the environment that promote a healthy lifestyle (attraction private investments in health promotion: increasing the number and popularity of fitness centres, sports sections, pools, services healthy eating, active recreation and domestic tourism, balneology and IT-products and digital solutions, monitoring of health promotion applications).

In order to create a unified statistical reporting and a unified electronic information system, there is a need to legislatively consolidate the obligation and responsibility of all medical organizations and healthcare entities independently of ownership in submitting information on the forms in the manner and terms established by the authorized body in the field of healthcare.

Statistical analysis and the introduction of forecasting mechanisms, based on actual and reliable health indicators, will allow us to plan and will implement a wide range of public health strategies aimed at improving lifestyle and reducing risk-taking behaviour.

Volunteering is becoming a new trend in modern Kazakhstan. It forms the participants' positive life values and responsibility for their country, increases trust between the state and society, gives rise to a sense of ownership. If we talk about healthcare, then volunteers make the industry more open, close to the population. In this regard, the Code will provide for rules that reveal the significance of the tasks of volunteers in medicine.

In order to create a unified statistical reporting and a unified electronic information system, it is necessary to legislate the obligation and responsibility of all healthcare organizations, regardless of ownership, in submitting information on the forms in the manner and terms established by the authorized body in the field of healthcare, and also provide for the introduction of statistical analysis and forecasting.

In general, the revision of the new Code will be the basis for the further development of a set of measures providing for the consolidation of efforts of central and local executive bodies, local self-government bodies, healthcare organizations, NGOs, the business community and citizens themselves, aimed at:

- reduction of premature mortality, morbidity, disability, increase in average duration and quality of life, improvement of the demographic situation in the country;

- maintaining an active working, social and personal life, as well as the realization of physical and intellectual potential;

- increasing the life expectancy of the population by maintaining reserves of health and health-saving technologies, by reducing morbidity and injuries, preventing premature and preventable mortality, primarily among working-age and childhood ages;

- the development of new, improvement and increase in the volume of existing recreational activities to promote health and disease prevention;

- preservation, restoration and strengthening of people's health;

- an individual approach to the assessment and correction of human health during his active working age;

- reducing the terms of health restoration by introducing modern diagnostic methods and integrated health technologies into healthcare practice;

- development and preservation of the country's labour potential through the formation and preservation of professional health, professional longevity;

- motivation, stimulation and promotion of a healthy lifestyle;

- ensuring interdepartmental and intersectoral approaches to improving the quality of life, improving working conditions, life and leisure of the population, the formation of a healthy lifestyle.

The principles of public health services will be:

- the availability of measures to assess the health status and health of the population, regardless of the social status of citizens, their income and place of residence;

- the priority of health and preventive measures in the field of public health;

- the continuity of recreational activities throughout a human’s life;

- a human’s responsibility for his (her) health and the health of his (her) relatives;

- implementation of the internal harmony of the physical, mental, spiritual state of a human, as well as harmony with the ecological and social environment;

- focus on the quantitative assessment of the reserve capabilities of the body and their correction for the realization of human health potential;

- consolidation of the actions of executive authorities of all levels, organizations and citizens in the formation and implementation of comprehensive programs for the protection of healthy human health;

- a multi-level approach to the organization of health and preventive measures, considering both the general needs of the country's population as a whole and the specific characteristics of the population of various regions, individual social, professional and age groups;

- the unity of the entire health care system, regardless of territorial and departmental distinctions;

- the unity of the preventive, health-improving and economic efficiency of the system of protection and promotion of health

Preventive and recreational activities will be aimed at all segments of the population and consider age and gender, psychological and social aspects:

Protecting the health of children: new-borns, children of primary and school age, which will provide them with a healthier start to life. The risk of developing congenital anomalies in children by a quarter is due to genetic abnormalities and environmental conditions, the abuse of alcohol drinks and drugs by the mother becomes an important factor.

The main causes of child mortality of the first year of life are individual conditions that occur in the perinatal period and congenital anomalies.

Among children over 1 year old - respiratory diseases, including pneumonia, external causes. Death from external causes largely depends on the social status of the family, the lifestyle of the parents. In addition, the potential danger of HIV infection and drug dependence of the new-born depends on lifestyle.

In the period after birth and until the age of 7 years, the priority will be measures aimed at ensuring each child the most favourable life start and will be accompanied by support and strengthening the health of the child: support for breastfeeding, the organization of a healthy diet, preparation for school, and elimination of harmful external factors.

It is necessary to legislatively introduce the concept of "school medicine" with the creation of child health centres in primary health care organizations that will deal with preschool and school children's health issues.

Currently, there is a tendency to increase refusals from vaccination, which will inevitably lead to the accumulation of a susceptible contingent to vaccine-preventable infections, which in the case of illness may cause serious complications up to disability and death.

Also, more frequent cases of parents refusing to vaccinate children can lead to the development of an epidemic of infectious diseases. For example, in 2017, WHO recorded about 24 thousand cases of measles, in 2016, a little more than five thousand. In 2018, the spread of infection continued - more than 900 cases of measles have already been reported, and there are reports of several dozen deaths.

The main reasons for the measles outbreak at WHO are the decline in overall coverage of routine immunization and the interruption in vaccine supplies. It is kindergartens and schools in the form of crowding that are the main place of infection with airborne infections. In this regard, it is proposed to strengthen the measure of parental responsibility in the form of refusal to accept unvaccinated children in organized groups, with the exception of cases when there are medical contraindications for vaccination.

According to this, it is necessary to legislate the mandatory prophylactic vaccination of children and strengthen the responsibility of parents for refusing vaccination. For example, in Italy, a fine for refusing vaccination ranges from two to seven thousand euros. Its size depends on the cost of treating the patient if he becomes ill or infects someone else. Vaccination in Italian pre-schools is required. In case of refusal of parents to vaccinate children, legislatively fix the refusal to accept unvaccinated children in organized groups (kindergartens and schools) in order to eliminate the risk of infection.

Youth health guard. Youth should be healthier and better prepared to fulfil their responsibilities in society. Particular attention is required during adolescence, the period when attitudes to nutrition, physical education, smoking, lifestyle, sexual behaviour are formed and risk factors for chronic diseases of older

age appear. The role of behavioural risk factors, including alcohol and drugs, offenses, unwanted pregnancy, is increasing.

International experience shows that improving the reproductive health situation can only be achieved by increasing youth's access to information, sexuality education and medical services through youth health centres and empowering minors to independently give voluntary informed consent to medical services.

In accordance with the Ottawa Declaration of the Rights of the Patient-Child (1999, 2009), informed consent is necessary for any diagnostic, treatment, rehabilitation or research procedure for a child. Accordingly, in the legislative practice of the Republic of Kazakhstan, there is a rule according to which, for minors, consent to medical intervention is given by their legal representatives, that is, the principle of voluntary consent to medical intervention applies only to parents in the Republic of Kazakhstan (*the Code of the Republic of Kazakhstan "On public health and healthcare system"*). At the same time, in many European countries, a number of CIS countries (Russia, Ukraine, Belarus, Georgia, Moldova), the USA, Canada, and Australia, the age of independent submission of voluntary informed consent for medical intervention is 14-16 years.

National study of reproductive health of adolescents and young people 15 - 19 years spent in the Republic of Kazakhstan with the support of UNFPA in 2012 showed that 64.6% of all young people have sexual intercourse at school age, until reaching the age of majority, at the same time:

- 13.6% of young people received their first sexual experience before the age of 15;
- at 15 years old - 27.2%;
- at 16 years old - about 30%;

In the Republic of Kazakhstan, the birth rate for teenage girls aged 15-19 remains unacceptably high - 28.13 in 2016, slightly decreasing compared to 2014, when it was 34.72 per 1000 girls in this age group. Every year, an average of 4-5 girls out of 1000 girls aged 15 to 18 years have an abortion. Low awareness, lack of skills in safe sexual behaviour, widespread sexually transmitted infections, high abortion rates and limited access to confidential reproductive health care for adolescents largely determine the situation in the country, when about 16% of couples turn out to be infertile at the time of adoption their conscious desire to have children.

Along with the problems associated with the reproductive health of adolescents, the growth of suicidal behaviour in this age group is of great concern. As of April 2016, 200 minors committed suicide. The most suicidal age group is adolescents 15-17 years old, they account for 60% of all suicides.

Adolescents and young people are not only poorly informed, but also have limited access to health services to protect their reproductive health, primarily due to lack of confidentiality. An additional limiting factor is the existing national legislation that does not allow adolescents to independently, without the support of parents or guardians, turn to medical institutions for reproductive health problems before they are 18 years old.

In this regard, it is necessary to legislatively consolidate the possibility of adolescents contacting medical organizations for consultative and diagnostic assistance without the consent of their parents and their legal representatives.

The reproductive health of women and the health of unborn children are need to pay particular attention, which requires: family planning skills, preventing unwanted pregnancies, ensuring safe motherhood, and preventing childhood disabilities.

In the period of 18-20 years, targeted measures will be taken to identify the risk of the emergence and treatment of emerging socially significant diseases, including cardiovascular, diabetes and tuberculosis, cancer: prevention of liver cancer through immunization against hepatitis B, cervical cancer through screening in parallel with the treatment of precancerous lesions.

Measures will also be taken to ensure the protection of mental health and the prevention of suicides among youth with the involvement of the education, labour and family protection sectors.

Protection and promotion of the workable population health.

A significant and sustained reduction in the number of injuries, cases of disability and death as a result of accidents and acts of violence, poisoning and injuries, major noncommunicable diseases (circulatory system diseases, respiratory diseases, digestive diseases). Exactly at this age, the difference in mortality between the population and the population of developed countries is maximum.

At the age of 40-59, diagnostics and correction of perceptible endocrine changes in the body will be carried out, as well as measures aimed at early identification of the risks of occurrence, early diagnosis and timely treatment of disorders of the musculoskeletal system (opening schools of osteopathy), cerebral blood circulation, breathing system and oncological diseases will be added.

Protection and maintaining health in old age.

People over the age of 60 should be able to fully realize their potential in relation to their own health and fulfil an active social role in society.

For older people, of particular importance is the extension of the terms of life, free from disability, in a state of health that allows you to maintain independence, self-esteem and their place in society.

In the first period of old age from 60 to 70 years, for people with preserved professional disability, competence and intellectual potential, measures will be aimed at supporting them, namely, improving health, reorganizing labour and improving working conditions considering the needs of older workers, as well as ensuring fitness workplace.

Medical measures will be aimed at the diagnosis and treatment of all diseases of the older age.

Another key task of public health will be to increase the effectiveness of sanitary and epidemiological surveillance and control, further measures to counteract the spread and reduce the consequences of especially dangerous infections, tuberculosis, HIV / AIDS.

One of the priorities of the healthcare system is to ensure the safety of food products, healthy and balanced nutrition.

International approaches to food safety are reflected in the Code of Alimentarius Commission standards, European Union directives, the Global Plan of Action for the Prevention and Control of NCDs for 2013–2020, and the WHO Food and Nutrition Action Plan for 2015–2020 years, regulations and standards of the Eurasian Economic Commission, as well as in national action plans.

At the same time, further improvement of the system of state control and supervision in the field of food safety, technical regulation and ensuring the reliability of conformity assessment procedures, production and circulation of safe products (goods) on the territory of the Republic of Kazakhstan is necessary.

Despite the current tendency to reduce the amount of non-conforming products (goods) subject to sanitary and epidemiological control (supervision), the main share of products (goods) sold on the country's market that do not meet the requirements of technical regulations and hygienic standards is imported and imported into the country under conditional release mode.

For example, in 2017, the volume of imported children's toys and products intended for children and adolescents that did not meet product safety requirements amounted to more than 48%.

The reasons for evading the procedure for assessing the conformity of products by participants in foreign economic activity is the small number of administrative fines that does not correspond to the cost of imported goods.

Activities carried out as part of desk control allow you to track the movement of products (goods) during customs clearance in the condition of conditional release and entry into the domestic market at the stage of its implementation, thus limiting the import and sale of goods that do not meet safety requirements.

To increase the effectiveness of supervision, cameral control provides for the introduction of information systems for all regions of the country, the intensification of interagency cooperation and the improvement of existing standards for taking operational measures in case of detection of non-conforming products that are circulated without documents, confirmation of compliance.

An effective mechanism for identifying non-compliance with the requirements of safety indicators is the selection of products (goods) at the implementation stage and laboratory examination, carried out in the form of preventive control and supervision with a visit to the subject (object) of control and supervision.

At the same time, the existing procedures for registering access to an object (when it is necessary to notify it of the upcoming selection of products at least a day before the start of the event) allows you to sell potentially dangerous products in the distribution network that have not passed confirmation (assessment) of compliance.

Also, the lack of the ability to conduct unscheduled inspections on the facts of detecting violations of labelling requirements contributes to the presence on the country's consumer market of food products, the labelling of which does not indicate expiration dates and storage conditions, reliable information on the composition of the product, its nutritional and energy value, and the content of prohibited food additives, preservatives, mass fraction of fat, genetically modified objects, DNA and much more. Human consumption of such products can lead to long-term illnesses, allergic reactions, obesity, diabetes mellitus and other noncommunicable diseases.

In this regard, it is supposed to continue work on improving the norms of national legislation, carried out in the form of preventive control and supervision with a visit to the subject (object) of control and supervision.

The quality of medical care is not up to the mark. Quality improvement measures should be implemented at all levels, and their impact on the effectiveness and quality of public health should be better controlled.

Imperfection of information systems does not allow to generalize medical data and to ensure continuous coordination of the provision of medical care to patients.

International approaches to food safety as an integral part are reflected in the Code of Alimentarius standards, EU directives, in the Global Plan of Action for the Prevention and Control of NCDs for 2013-2020, in the WHO Plan of Action for Food and Nutrition for 2015-2020 and others.

Also, in the implementation of the requirements of the Eurasian Economic Commission and the World Trade Organization, norms are provided for the implementation of the requirements of supranational legislation of the EAEU member states in the field of technical regulation. These standards are necessary to improve the system of state control and supervision in the field of technical regulation and ensure the reliability of conformity assessment procedures, in order to ensure public safety, create conditions for fair competition, production and circulation of safe products on the territory of the Republic of Kazakhstan.

Despite the downward trend in the number of non-conforming products subject to sanitary and epidemiological control, the bulk of non-conforming products (goods) generally sold on the country's market are imported and imported into the country under conditional release mode, safety monitoring is an effective mechanism for identifying products (goods) products carried out in the form of preventive control and supervision with a visit to the subject (object) of control and supervision.

The complication of the procedure for registering access to an object (at least one day before the start of the event, it is necessary to notify him of the forthcoming selection of products) allows you to sell potentially dangerous products on the country's markets that have not passed the conformity assessment. In 2017, the volume of only toys that did not meet the safety requirements of products imported and sold in the country amounted to 48%.

At the same time, the goal of adopting all technical regulations is to protect human life and (or) human health and prevent actions that mislead consumers. The inability to conduct unscheduled inspections of violations of labelling requirements contributes to the presence on the country's consumer market of food products whose labelling does not indicate expiration dates and storage conditions, the manufacturer does not accurately indicate the composition of the product, its nutritional and energy value, the content of prohibited food additives, preservatives, mass lobes of fat, GMOs, DNA and more. Human consumption of such products can lead to long-term illnesses, allergic reactions, obesity, diabetes mellitus and other noncommunicable diseases.

Also, in accordance with the Article 202.1.2 of the Code of the Republic of Kazakhstan "On Customs Regulation in the Republic of Kazakhstan", it is stipulated that goods that are subject to restrictions in respect of prohibitions and restrictions in accordance with the Treaty of the Union and (or) the legislation of the Republic of Kazakhstan may be confirmed after the release of goods. However, as the results of cameral control show, the above requirements are not always observed by participants in foreign economic activity.

Cameral control will allow tracking goods during customs clearance of goods in the condition of conditional release and release into domestic consumption to comply with the requirements established by the EAEU and the Republic of Kazakhstan, at the stage of its implementation (will limit the import and sale of goods that do not meet safety requirements in the country).

The reasons for the facts of evading the procedure for assessing the conformity of products, participants in foreign economic activity is the small number of administrative fines that do not correspond to the cost of imported goods.

The presence of illegal import of goods in the Republic of Kazakhstan has a negative impact on the life and health of citizens. Thus, in order to ensure the safety of the population and increase efficiency and effectiveness, cameral control provides for standards that enhance interagency cooperation, as well as improvement of existing standards for taking measures in case of detection of non-conforming products.

The quality of medical care is not up to the mark. Quality improvement measures should be implemented at all levels, and their impact on the effectiveness and quality of public health should be better controlled.

Imperfection of information systems does not allow to generalize medical data and to ensure continuous coordination of the provision of medical care to patients.

II. Improving the Medical Care System

International reviews of Kazakhstan's health system indicate that Kazakhstan, compared to other countries with similar levels of GDP per person, continues to lag behind the average life expectancy at birth. The average life expectancy at birth was 72.4 years in 2017, which is about eight years less than the average for OECD countries in the Baltic countries, as well as in Central Europe, which have approximately the same level of GDP at per person, as in Kazakhstan, the average life expectancy at birth is much higher. There are countries with lower GDP per person and much higher life expectancy at birth than in Kazakhstan.

This indicates that in addition to the issue of further increasing health care spending, increasing the effectiveness of the national health care system will also be crucial for Kazakhstan.

The implementation of the current Code of the Republic of Kazakhstan allowed introducing fundamentally new relationships in the industry, for the country to enter the 50 most competitive countries in the world.

At the same time, an assessment of the implementation of state programs for the development of health care in the Republic of Kazakhstan demonstrates the existing system deficiencies, without which it is difficult to further improve the health of citizens of the republic.

Achieving the goal of becoming one of the 30 most competitive countries in the world requires the system to quickly group its efforts to build a new, long-term healthcare model based on the best examples of its own and international experience, which will ensure the availability and quality of medical services, while maintaining financial stability while any fluctuations in the global and domestic economies.

Based on the foregoing, the new version of the draft Code will be aimed at consolidating and developing the successes achieved and solving the existing problems in health issues, and will also become the basis for the planned and progressive development of the industry until 2050.

Ensuring universal access to health services is the basis for the implementation of the Sustainable Development Goals until 2030.

The goal of universal access to health services is to provide all people with the necessary medical services and reduce the financial burden of paying for them through the establishment of strong health systems, financing of medical services, access to essential medicines and the sufficient potential of well-trained health workers.

The norm on the availability of medical insurance for foreigners temporarily residing in the Republic of Kazakhstan does not solve the issues of medical care for these categories of people, primarily due to the lack of mechanisms for its implementation. In addition, the presence of illegal labour migration creates great risks not only for the foreigner, but also for citizens of the Republic of Kazakhstan.

The availability of health insurance for a foreigner is only voluntary insurance, which, as a rule, does not cover expenses in the presence of diseases requiring long and costly treatment, such as tuberculosis, HIV infection. Today, no insurance company is interested in insuring sick people with chronic costly diseases.

In this regard, deductions of employers to the compulsory health insurance fund for working temporarily resident foreigners will allow legalizing labour migration, as well as ensuring the availability of medical care for temporarily residing foreigners.

Regarding this, universal coverage is a measure of government commitment to improving the well-being of all its citizens. At the same time, countries should monitor progress not only at the level of the population of countries, but also at the level of different groups, considering their income, gender, age, place of residence, migrant status and ethnic origin.

To ensure universal health coverage, the following are required:

- a robust, effective, well-managed health system that meets the basic health needs of people, including services for HIV, tuberculosis, malaria, noncommunicable diseases and maternal and child health by:

- providing people with information and urgent recommendations regarding the preservation of health and disease prevention;

- early detection of health problems;

- building capacity for the treatment of diseases;

- assisting patients in rehabilitation.

Over the past decade, life expectancy at birth has risen rapidly, but significant potential for improvement is maintained. Despite progress, life expectancy in Kazakhstan at birth is well below the OECD average. In particular, it still lags behind OECD countries with the same level of GDP per person or health expenditures per person.

In Kazakhstan, life expectancy is also characterized by one of the largest gender gaps - almost twice the average gender gap in life expectancy in OECD countries.

Over the past two decades, infant and maternal mortality decreased by four and six times, respectively, which allowed Kazakhstan to achieve the relevant goals of the Millennium Declaration (hereinafter – "**the MD**") and to approach the OECD average. There is also a low mortality rate from infectious and parasitic diseases, but tuberculosis is an alarming exception.

Despite significant achievements in the national healthcare system of Kazakhstan and the successes of the reforms undertaken over the past two decades, the healthcare system in the country is under increasing stress from the growing burden of chronic diseases and needs a systematic transformation of its structure.

First of all, there are high mortality rates from diseases of the circulatory system and chronic diseases of the lower respiratory tract, such as chronic obstructive pulmonary disease (hereinafter – "**the COPD**"). Cancer survival is also low, and cancer is the third leading cause of death.

Given the current state of public health and the projected increase in diseases, the draft Code will introduce an integrated model for organizing medical care. Under this model, the rules, procedures and standards for the provision of integrated medical care will be implemented, aimed at ensuring its completeness, quality and continuity at all levels of the healthcare system.

The currently fragmented medical services do not allow for the provision of effective and comprehensive medical services for the population.

In this regard, it is necessary to create a clearer vision of the future architecture of the health system. They should be classified in a way that balances community service availability and appropriately focuses limited resources at higher levels of the system.

Thus, a new approach to the organization of medical care according to international experience will be regulated, providing for a three-tier system of medical care.

The provision of three-level medical care (primary, secondary, tertiary) allows you to control the flow of patients (triage of the system) at all levels, as well as the willingness to accept patients of any profile in hospitals. This approach will help improve hospital management by optimizing the flow of patients by differentiating the bed capacity according to the degree of treatment intensity, medical rehabilitation and aftercare, and strengthen the third-level responsibility for the introduction of new treatment methods and technologies, which will make it possible to meet the expectations of the population regarding access to high-tech health services. Such optimization opens up real opportunities for increasing the efficiency of the healthcare system.

With the introduction of a three-tier system of medical care, legislative approaches will be revised to determine the types, forms, and conditions of medical care.

The leading role of chronic noncommunicable diseases in the development of morbidity and mortality requires a change in approaches to the management of patients with these diseases and the creation of a chronic disease management system. In this regard, the concepts of "management of chronic diseases" will be legally defined, and approaches to the definition of "socially significant diseases and diseases that pose a danger to others" will be revised.

The concepts of "emergency medical care", "paramedics", as well as the definition of "first aid" and the procedure for providing first aid to paramedics, will be legislated.

The principles of protecting mental patients and improving mental health will also be expanded in line with the principles for protecting the rights of mental patients with the resolution of the UN General Assembly of December 17, 1991.

Since 2009, in the Republic of Kazakhstan, screening studies for the early diagnosis of chronic diseases have been introduced, but the concept of screening studies is not provided for by law. In this regard, there is a need for legislative consolidation of the concept of "Screening studies" and determine the order of their conduct.

The organizational structure of the Kazakhstan health system today is largely equal to the structure of the most successful OECD countries. Reforms in general are moving in the right direction. However, there is an incomplete and ineffective implementation at all levels of the health system. Not enough attention is paid to assessing real progress in their effective implementation.

It is necessary to strengthen and coordinate more effectively the reorganization of this sphere. In the coming years, the healthcare system should consistently focus on more modern mechanisms with a clear emphasis on improving indicators of the state of public health and maximizing efficiency.

In order to provide all citizens with effective, high-quality health care and reduce the incidence of chronic diseases, it is necessary to improve the placement of strategic priorities in the health system and, in particular:

- focus on reducing the incidence of chronic diseases. The main goal of future reforms should be to overcome the level of diseases amenable to medical interventions. Priority should be given to the treatment, control and targeted prevention of chronic, noncommunicable diseases;

- redouble efforts to restore balance in the provision of medical services in favour of primary health care.

Strengthening the system of providing services at the PHC level and improving the management system should remain a priority in the field of medical care for the population.

The experience of OECD countries suggests that, in many cases of chronic disease, it is possible to effectively and cost-effectively treat or prevent prophylaxis at the PHC level.

Thus, further optimization of hospital services and the development of primary health care can offer real opportunities to improve the efficiency of the system.

It is necessary to improve the procedure for the provision of secondary care and the improvement (strengthening) of balneology, medical rehabilitation in all areas, as well as to change the mechanisms for financing medical services and the tariff policy. New concepts such as "multidisciplinary approach and team" and "balneology" will also be introduced.

In order to prevent the causes of safety violations in transport, it is necessary to regulate the issues of pre-shift and post-shift medical examinations.

It also requires improvement of issues related to the activities of medical services of law enforcement agencies, the public service, and the penal system, including the expansion of their competence in the development and approval of special statistical reporting forms, etc.

In addition, legislative regulation of sports medicine, etc. is necessary.

Intravital consent to organ donation. The mechanism of each citizen for lifetime consent will be legally regulated by registering consent in one of the official documents (identity card, driver's license). The issues of coordination of transplantation, transplantation of artificial organs will be regulated.

Issues of organ and tissue transplantation from living and cadaveric donors are regulated in the current Code of the Republic of Kazakhstan "On public health and healthcare system". As well as a by-law, in particular, an order of the Ministry of Defence of the Republic of Kazakhstan, a mechanism has been provided for granting in vivo consent of citizens to donation.

As for the coordination of transplantation of artificial organs, international experience shows the possibility of growing artificial organs using new technologies. In this regard, it is likely that such technologies will be introduced in Kazakhstan. The new Code will regulate the transplantation of artificial organs and tissues through the development by the authorized body of the procedure for their implementation.

Also, in order to prevent the criminalization of the removal of tissues and organs, including cadaveric ones, the procedures for granting lifetime consent to donation and the priority of close relatives who may express disagreement with cadaveric donation will be reviewed and regulated.

Organization of medical assistance to athletes. It is necessary to legislatively unify the organization of medical care and dynamic monitoring of athletes. These services are medical and should be included in the package of the guaranteed volume of free medical care (hereinafter – "**the GVFMC**" or compulsory social medical insurance (hereinafter – "**the CSMI**" however, today there is no unified procedure for providing medical assistance to this category of the population, respectively, in each region there are different financing mechanisms.

Activities of draft commissions. It is necessary to legislatively unify the activities of draft commissions to avoid duplication of services. Today, the situation on the activities of draft commissions varies in the regions. As a rule, doctors from the healthcare system, who are the only ones in the medical organization, are involved in the draft board. Accordingly, medical care suffers for other patients and is not performed by the GVFMC. In fact, these are the same medical preventive examinations that are carried out in schools and universities. At the same time, the system of continuity in obtaining data from a routine examination has not been built today, poor-quality examinations take place. In this regard, duplication occurs. In addition, the draft commission often appoints additional studies to draftees who are not members of the GVFMC. In this regard, it is necessary to legislatively regulate the standard of medical care for draftees with the definition of the necessary amount of funding and the establishment of continuity at the stages of medical examinations of draftees.

The list of specialties of employees of state healthcare organizations that provide benefits for early retirement due to occupational hazards. In order to maintain an experienced contingent of key medical specialists in the state segment. It is necessary to legislatively determine the competence of the authorized body in the field of health in the development and approval of the list of specialties of employees of **state health organizations that** are entitled to benefits in receiving allowances and early retirement.

In addition, the development of modern technologies for the treatment of patients using nuclear medicine, photon, proton rays also increase the risks of occupational diseases, disability, premature death of health workers, the development of radiation sickness, as well as cancer incidence. In this regard, and also considering the specifics of the medical industry, it is proposed to develop a separate list of specialties that will provide benefits for early retirement, alternative benefits, and also determine the procedure for their provision.

The right and duty of the employer for social protection of medical workers, in case of infection and the development of the disease in the course of professional activity, which does not allow working in the specialty. Retraining at the expense of the employer and further employment. The right to receive extraordinary free medicines in case of treatment of this disease as part of outpatient medicine provision (hereinafter – "**the OMP**"), as well as to receive all necessary consultative and diagnostic services within the framework of the guaranteed volume of medical care.

Providing mandatory statistical reporting in the manner and terms established by the authorized body in the field of health care by healthcare organizations, regardless of ownership or departmental affiliation. In order to create a unified statistical reporting and a unified electronic information system, it is necessary to legislatively consolidate the obligation and responsibility of all medical organizations in submitting information in forms in the manner and terms established by the authorized body in the field of health.

In connection with the introduction of the CSMI system, the issue of providing medical assistance to military personnel, employees and other employees of law enforcement, special state bodies and civil protection bodies, members of their families, and pensioners of this category of people needs to be resolved.

In order to ensure equal access to medical care, the procedure for providing medical care to military personnel, employees and other employees of law enforcement, special state bodies and civil protection bodies, members of their families, pensioners of this category of persons, within the framework of the GVFMC and the CSMI system will be unified.

The instrument of joint responsibility of citizens and the introduction of a co-payment mechanism for medical care and medicines require regulatory fixing. Today, the burden of ensuring health protection lies only with the state, while citizens themselves have not formed an adequate level of responsibility for their health (timely passage of dynamic monitoring, participation in recreational activities, abandonment of bad habits and more).

The norms of joint responsibility for health, in particular the rights and responsibilities of workers and employers, the creation of conditions for the protection of health, the provision of time by the employer during working hours for routine inspections, will be spelled out in the Code, as well as in other relevant laws governing labour relations.

According to experts from the World Health Organization, a person's life expectancy and state of health only 10% depends on the level of development of medical care and health services, 20% on heredity, another 20% on environmental conditions, and 50% is determined by a person's lifestyle and nutrition. Thus, human health is most dependent on lifestyle. Until the last decades, national health systems did not include cost-sharing mechanisms in guaranteed health care programs. The publication of the results of the experiment of introducing co-payments and the subsequent experience of using the cost-sharing mechanism in private health insurance made it possible to change the attitude towards this tool. OECD countries have positive experience. So, in the last decade, the idea of using different levels of participation in payment to promote rational consumer behaviour in everyday life (giving up bad habits, playing sports) or when consuming medical services (referring to medical specialists in the direction of a primary contact doctor, going through a chronic school) has gained popularity. diseases, regular medical examination, screening). This is the mechanism for implementing measures when a patient who is disciplined and responsible for his health will receive help for free, and if the doctor's recommendations and regulations are not followed, the patient will be forced to pay co-payment. The mechanisms for sharing costs between the patient and the holders of the health system budget funds for medical care and medicines should be considered as motivating patients to have a healthy lifestyle and as an essential factor in restraining the growth of costs in the provision of medical care.

As part of the implementation of the National Drug Policy, in accordance with the approved State Program for Health Development of the Republic of Kazakhstan "Densaulyk" for 2016 - 2019, it was supposed to provide for the possibility of the population choosing more expensive drugs on the basis of co-payment by the citizens of the difference in the cost of these drugs and the established maximum price for reimbursement. In Article 4 of the current Code "On public health and healthcare system", the current law on compulsory social health insurance already stipulates the principle of joint responsibility of the state, employers and citizens for maintaining and strengthening individual and public health.

The mechanisms for the formation of joint liability will be determined by the regulatory legal act of the authorized body.

The procedure for co-payment for medical care and medicines will be determined by the authorized body.

Pursuant to the instructions of the Head of State N. Nazarbayev, voiced in a message dated January 10, 2018, "New Development Opportunities in the Conditions of the Fourth Industrial Revolution," work continues on a phased transition to the system of compulsory social medical insurance (hereinafter – "**the CSMI**") based on joint and several liability population, state and employers.

Considering the instructions of the Head of State, as well as the continuing risks in obtaining medical care by the uninsured population, new approaches to the formation of the list of the guaranteed volume of medical care and the package of medical care in the CSMI system have been developed.

Interdepartmental work continues to formalize and involve informally employed people in the country's economy and in the CSMI system.

It is also important that service providers are accountable and provide quality services. Improving the coordination of the provision of medical services is a prerequisite for improving the quality of medical care and gaining the necessary experience, especially for patients with complex needs.

Thus, a legislative solution to the issue of the efficient use of financial resources and the responsibility of suppliers for the quality of medical care, regardless of ownership or departmental affiliation, is necessary.

Any specific revision of the guaranteed volume of free medical care (hereinafter – "**the GVFMC**") should ensure the provision only of those activities, that are cost-effective.

In this way, the main circumstances in the development of the new Code are:

- a need to ensure a healthy, active and creative life of the population as the main task of state social policy;

- a recognition of the role of public health as a strategic potential, a factor of national security, stability and well-being of society;

- a need to focus on health, which plays a key role in human competitiveness, family well-being, and professional development;

- a need to form a culture of health, mechanisms for maintaining, strengthening health in the process of individual development and realization of a person's potential, considering genetic, physiological, psychological, intellectual, generative functions.

Further restructuring and development of health care should be accompanied by additional efforts to improve quality. In addition to existing quality initiatives, such as the use of clinical guidelines, accreditation processes, and ways of providing care, new quality improvement measures should facilitate periodic monitoring of health indicators, for example, by creating incentives for reporting.

At the same time, the concept of a "culture of quality assurance in medical organizations" needs to be legislated. Reporting and promoting the quality of care, rather than punitive measures, can also increase the involvement of healthcare providers in the provision of quality medical care.

The experience of OECD health systems suggests that publicly reporting data at the service provider level on the most common health indicators increases awareness of the differences between service providers, stimulates discussion of ways to improve data reliability, and directs efforts to improve indicators. The participation of healthcare providers will be most significant in an open, constructive environment.

Patient orientation in the three-level system of medical care will be ensured by strengthening work with non-governmental organizations and public associations, through improving standards, clinical protocols for diagnosis and treatment, developed on the basis of evidence-based medicine and the results of the evaluation of medical technologies.

International experience shows that the results of the transfer of functions by the state are successful in mutual cooperation.

It is necessary to legislatively strengthen and modernize the system for providing clinical practice standards. The various guidelines and protocols developed do not have a clear legislative regulation of their approval and application in practice.

Thus, when providing medical care, specialists should be guided by clear standards that determine the procedure for organizing effective joint work and cooperation of various specialists in the provision of primary health care (PHC) and other related fields.

Further reform of the health care system will be based on the formation of an infrastructure that flexibly responds to the needs of the population in affordable, comprehensive, high-quality medical services.

Here, the platform will be the updated standard of the network of healthcare organizations, which will be based on modern planning approaches.

New approaches to planning a network of healthcare organizations will make the standard of the network more flexible and oriented to the needs of the population, and will also increase the availability of medical care.

The updated network will be aimed at providing medical care to a certain number of people in a certain territory, which will exclude duplication of facilities.

Measures will be taken to ensure access to services in remote and rural areas, and inequalities between regions in access to health services, as well as between cities and rural areas, will be eliminated. Problems associated with geographical remoteness and low population density, demographic indicators, and characteristics of the age and sex composition of the region will be considered when planning the provision of medical care.

Implementation mechanisms will be prescribed in the Code and implemented through the competence of the authorized body to develop standards for a network of health care organizations in rural areas, depending on the population, density, geographical distance from the regional centre, determine the necessary volumes and standards of medical care in rural areas, including considering the age and sex composition.

Legislatively, standards for the provision of medical care at the level of rural health care will be enshrined, as well as standards for the material and technical equipment of rural health organizations, considering regional characteristics.

State investments will be planned and directed to the development of the healthcare network in areas where the use of concessions and public private partnerships (hereinafter – "**the PPP**") is limited, there is no economic feasibility of its development, as well as in sectors strategically important for the development of the industry (motherhood, tuberculosis, HIV, and so on).

The systematization and regularity of investments will be ensured on the basis of a single long-term plan for healthcare infrastructure.

In this regard, the introduction of a unified long-term plan will make it possible to effectively plan investments and allocate resources based on the goals and priorities of the industry development, increase attractiveness for private sector participation, and satisfy the needs of the population in the regions in updating the infrastructure.

The modernization of the hospital sector will continue through the reorganization of the medical services delivery system, increasing efficiency, and ensuring access to quality care, considering regional needs.

Infrastructure development will be ensured through systematic planning, considering the new state standard for a network of healthcare organizations and regional needs.

At the stationary level in the village, medical care will be concentrated at 2 levels: district and inter-district hospitals.

In this way, specialized medical care in narrow profiles (urology, neurology) will become more accessible to the rural population due to the organization of inter-district hospitals based on a number of district hospitals.

Consultative and diagnostic assistance will be concentrated at the level of hospital organizations, which will improve the quality of diagnostics and the provision of resources through consolidation.

Also, in cities, single-discipline hospitals are integrated into multi-field hospitals. Thus, specialized centres will develop on the basis of multidisciplinary hospital organizations.

At the national level, by 2025, a number of existing health research organizations will be integrated into university clinics.

It is necessary to change approaches to the profiling and re-profiling of the hospital bed capacity in order to adapt to changes in rapidly changing legal and financial conditions, to satisfy the needs of the patient and to be accountable.

III. Enhancing educational and scientific activities in the field of healthcare.

One of the fundamental conditions for creating an effective healthcare system is to provide the industry with competitive specialists, demanded scientific developments and innovations. Implementation of the State programs for healthcare development such as "Salamatty Kazakhstan" for 2011-2015 and "Densaulyk" for 2016-2019 allowed to take a set of measures to improve the existing system of medical education and science, including the introduction of mandatory residency in the training of medical personnel and programs after secondary education for the training of nursing personnel of the new formation, consolidation at the legislative level of training in clinical specialties as prerequisite, the formation of university clinics and (or) integrated academic medical centers, the determination of the basic conditions for the implementation of strategic partnerships in medical education and science organizations.

One of the important components of the quality of medical personnel is the assessment of students' knowledge. In this regard, the assessment of the knowledge and skills of students enrolled in medical education programs was enshrined in law. To ensure the independence of the assessment procedure, the National Center for Independent Examination was established and the competence of the authorized body in the field of healthcare in accrediting organizations that assess knowledge and skills was consolidated.

The modernization of the system of medical education, the introduction of innovative forms and methods of training make high demands on the personality and professional competence of teachers in medical organizations of education and science. In this regard, it was proposed to consolidate at the legislative level an assessment of the competencies of scientific and pedagogical personnel of medical education and science organizations.
All these innovations made it possible to create the necessary legal framework for the implementation of generally accepted world approaches in the training of specialists in the field of healthcare.

At the same time, a number of problems remain unresolved, including the imperfection of educational programs and their low connection with the needs of practical health care, insufficient practical training of students, and low efficiency of the academic setting in medical education.
Overcoming these problems requires the further implementation of the best international standards in the field of medical and pharmaceutical education, including on the basis of studying the experience of Nazarbayev University and leading world universities - strategic partners of domestic medical universities.

The new edition of the Code should reflect the issues of expanding the academic and administrative independence of medical education organizations, including the reorganization of medical universities into non-profit organizations, granting them the right to independently develop educational programs in accordance with the demands of the labor market, and independently solve the issues of formation of the contingent of students and the cost of training, etc. The optimal legal form is "non-profit joint-stock company."

The new edition of the Code should also reflect the best international practice of implementing residency and continuing education programs, including through the implementation of post-doctoral programs that provide in-depth training for clinical practitioners and researchers.

To create an effective academic setting in the new edition of the Code, mechanisms for implementing the strategic partnership of medical education organizations, the conditions for the establishment and basic principles of university clinics and integrated academic medical centers should be further developed.
The modernization of the medical education system, the introduction of innovative forms and teaching methods make high demands on the professional competence of teachers of medical universities and colleges. In this regard, the new edition of the Code should reflect the issues of training, professional development and assessment of teachers, as well as determine the legal framework for the activities of clinical mentors.
Giving academic independence to medical education organizations, on the other hand, it is necessary to introduce legal mechanisms to ensure appropriate qualifications for graduates of medical education programs, including on the basis of determining the list of basic competencies of graduates of medical education programs, transforming the system of independent assessment of knowledge and skills of

students studying medical programs education in licensing exam. Following the example of leading foreign countries (USMLE and NCLEX in the USA, IFOM in a number of European countries, etc.), the licensing exam should form the basis of the licensing procedure for medical workers introduced in the Code.

The quality control of the activities of educational organizations in world practice is carried out through a system of licensing, post-licensing control and accreditation. In this regard, the Code should reflect the rules governing issues of post-licensing control and independent accreditation of medical education organizations, including considering the specifics of personnel training for the health care system. It is also necessary to strengthen the requirements for organizations that implements programs of additional medical education.

Development of a research system in the field of medicine and improving the quality of bioethical examination.

As part of the implementation of the State Health Development Program of the Republic of Kazakhstan "Densaulyk" for 2016-2019, it is planned to modernize methodological approaches in domestic medical science based on the transfer of advanced world standards and concepts, integration domestic scientific programs with international ones, and involving domestic researchers in international multicenter research programs.

In order to harmonize and optimize the legislative framework that regulates the procedure for conducting research in the field of medicine in the Republic of Kazakhstan, it was proposed to introduce norms in the Code of the Republic of Kazakhstan that regulate the requirements for fundamental biomedical and non-clinical applied research. Along with simplifying the legal mechanisms of regulating clinical trials, the Code proposed the inclusion of key standards that reflect modern, accepted by the international scientific community, requirements for conducting research in the field of medicine, including expanding the list of vulnerable research subjects (due to the students, the elderly persons, staff of medical organizations, etc.) and the regulation of the conditions for their inclusion in research, strengthening the role and status of Ethics Commissions (based on the transition to the concept of bioethics, covering all areas of research, the introduction of certification of local bioethics commissions), the introduction into the legal regulation of biobanks - specialized repositories of biological materials for scientific and medical purposes.

All these innovations made it possible to create the necessary legal framework for the formation in Kazakhstan of a research environment that meets international standards and requirements.
At the same time, the competitiveness and the level of integration of domestic medical science into the world research space remain at an insufficient level, and the imperfection of the procedure for transferring research results to clinical practice is noted.

Overcoming these problems requires the further implementation of the best international standards and research methodologies in the field of medicine.

In this regard, the new version of the Code should reflect the legal framework for the development of translational medicine, based on the accelerated transfer of research results to clinical practice, including Terms of use of the latest scientific developments in medical activities in respect of which clinical trials are being conducted.

Necessary conditions must be created for the further development of healthcare in the direction of highly scientific technologies, genetical, regenerative and nano-medicine. At the same time, the Code should regulate the conditions for research and development, which are based on genetic research, cell technology, 3D-printing.

International experience indicates the presence at the national level of legislatively established standards governing the activities of biobanks, *high-quality centers (Excellence Centers)*.

Along with these innovations, it is necessary to include in the Code the norms that ensure the further strengthening of the role and status of the Bioethics Commissions, the inclusion in the Code's scope of regulation of all types of medical research, including epidemiological research, health system research, etc.

All this will improve the quality of research and ensure the development of international cooperation in the field of medical science.

IV. Improving pharmaceutical activities and the circulation of medicines and medical devices.

In accordance with the introduction of new terms and definitions within the framework of the adopted acts of the Eurasian Economic Union for their application in national legislation, as well as the elimination of conflicts in law enforcement practice, it is necessary to bring them into line with the inclusion of a number of new concepts.

The global medical device nomenclature (hereinafter – "**the GMDN**") is a system of internationally agreed general concepts used to identify all medical items. The GMDN is used by regulatory authorities of the countries of the European Union, the USA, Japan and other countries and in fact is a single platform for identifying medical devices and international industry-wide information exchange. This term is also used in regulatory legal acts of the Eurasian Economic Union (hereinafter – "**the EAEU**"). The Nomenclature of Medical Devices of the Republic of Kazakhstan (hereinafter – "**the NMDRK**") is a systematic nomenclature classification of types of medical devices, harmonized with the GMDN and used in the Republic of Kazakhstan. The creation of the NMDRK will allow solving a number of problems: optimization of the search, purchase and registration of registered medical devices for healthcare subjects, data structuring in the compulsory medical insurance system, and inclusion of medical devices in the tracking system, quality control, efficiency and safety of medical devices.

In order to eliminate the legal gap and clarify the concepts related to medicine provision, it is necessary to clarify the definitions of "marginal price of medicines and medical products", "mark-up on medicines and medical products".

In accordance with the State Health Development Program "Densaulyk" for 2016 - 2019, the Republic of Kazakhstan sets a goal to enter the International System for Cooperation of Pharmaceutical Inspections (hereinafter – "**the PIC/S**"). Membership of the Republic of Kazakhstan in this international organization will allow harmonizing national standards and procedures in the field of inspection of manufacturers of medical products and will provide an opportunity for mutual recognition of inspection results through the use of equivalent standards and procedures. The main requirement for joining PIC/S is the compliance of the country's legal framework for licensing the production, distribution of medicines, as well as for the pharmaceutical inspection (GMP/GDP) with the requirements of PIC/S. One of the important conditions for licensing the production and distribution of medicines under the PIC/S guidelines is the compliance of facilities and entities with GMP/GDP requirements.

The implementation of good pharmaceutical practices and the preparation of Kazakhstan for entry into the International System of Cooperation for Pharmaceutical Inspections PIC/S, necessitate the inclusion in the state regulation system of standards for conducting pharmaceutical inspections of facilities and entities in the field of circulation of medicines and medical devices for compliance with good pharmaceutical practices and system requirements quality of a medical device manufacturer, and the delineation of functions between state control and the pharmaceutical inspection. In this regard, it is necessary to introduce the relevant requirements into the new Code and the Law of the Republic of Kazakhstan "On permits and notifications".
The above measures also correspond to acts adopted within the framework of the EAEU.

The development of domestic pharmaceutical production is one of the priority tasks within the framework of the «Densaulyk» state program. In order to achieve this goal, it is necessary to create conditions conducive to the development of domestic production and to minimize possible legal and bureaucratic barriers. In this regard, it is proposed to legislatively give priority to manufacturers of medicines and medical devices of the Republic of Kazakhstan during the examination for state registration, re-registration and amendments to the registration dossier. This amendment will accelerate the time for the release of domestic medicines and medical products to the market of the Republic of Kazakhstan and beyond.

One of the conditions for domestic medicines to enter the common market of the EAEU countries is the compliance of production conditions with the requirements of good manufacturing practice. In this regard, the EAEU Acts determined a number of measures necessary for implementation within the framework of national legislation.

So, to create a unified register of authorized persons of the EAEU, the need for a certified authorized person is determined. For this purpose, it is necessary to introduce a standard for certification of authorized

persons and provide for the creation and maintenance of an appropriate register. Also, as part of the creation of a common EAEU market, it is necessary to introduce clarifying standards in terms of contract manufacturing and the status of medicines manufactured under the contract.

Medicines, their safety, effectiveness and quality are a factor of national security. Requirements for safety, efficacy and quality are constantly increasing due to the development of more complex medicine using biological molecules. To create a market for quality medicines and medical devices, it is necessary to adapt national legislation to international requirements.

In this regard, in the draft new Code it is necessary to harmonize it with international requirements on the following issues:

• declaring all manufactured products and introducing a system for withdrawing products from the market using risk-based approaches;
• introducing a surveillance system from production to the use of medicines and vaccines;
• systems for monitoring the safety, quality and effectiveness of medicines;
• improving the formulary system and rational use of medicines;
• improving the licensing system by introducing a system of pre- and post-licensing inspection;
• introduction of a system for assessing healthcare technologies, compiling lists of medicines and within the framework of the guaranteed volume of medical care and medical insurance;
• regulation of prices for all medicines;
• introducing ethical promotion of medicines.

Moreover, according to the benchmarking of the National Regulatory System, the World Health Organization recommended the improvement of the following areas:

1. Consolidation of all regulatory functions in one body;
2. To align Licensing and Inspection in line with WTO recommendations and best standards and practices;
3. Implementation of a quality management system at all levels;
4. Strengthening post-marketing control with the introduction of a risk-based approach;
5. Consolidation of supervision for all medical products (medicines, vaccines, medical devices).

A constant change in the policy of registration of medicines is caused by changes in objective factors in the conditions of circulation of medicines, new approaches to admission to the market, and to ensure safety, efficiency and quality.

In order to move from a quality control system to a quality assurance system, it is also necessary to provide harmonization with the international requirements of the Organization for Economic Co-operation and Development (hereinafter – "**the OECD**"), since the measures used by these countries create an effective system of post-registration control and allow counteraction to the illegal production, import and circulation of medicines.
One of the effective measures is the creation and implementation of a system for tracking medical products in the Republic of Kazakhstan. It is necessary to supplement the competence of the authorized body in terms of the development and approval of rules for tracking medicines.
In order to create a quality assurance system, it is proposed to introduce a number of the following measures at the stage of pre- and post-registration control of medicines, medical devices and vaccines:

• declaration of products without laboratory tests;
• withdrawing products from the market for quality control, considering a risk-based approach;
• inspection of enterprises once every 3 years;
• issuance of conclusions of the registering authority on the basis of the "one-stop shop" principle.

To clarify the concepts associated with the rational use of medicines in the new Code, it is required to introduce a separate article "The rational use of medicines", which will spell out the key points for ensuring compliance with this norm, as an integral element of the quality of medical care.

For the effective implementation of the above tasks, it is necessary to simultaneously develop and bring into line with by-laws and regulations on the formation of the Kazakhstan national medicine form, based on the proven clinical efficacy and safety of medicines, and to ensure transparency of processes and the quality of medical care and rationalization of the use of high-quality, safe and effective medicines.

In order to implement measures related to the introduction of state regulation of prices for medicines, it is necessary to empower the authorized body for state control in the field of circulation of medicines, medical devices and medical equipment in part:

- examination of external reference pricing;
- implementation of risk and cost sharing systems;
- determining the optimal registration price.

The procurement by the Social Health Insurance Fund (hereinafter – SHIF) of pharmaceutical services from a single distributor within the guaranteed volume of free medical care, as well as the purchase of pharmaceutical services and services from healthcare providers as part of the provision of medical care in the compulsory social health insurance system, are not clearly regulated. In order to eliminate the gaps in the legislation and the smooth functioning of the fund and its interaction with healthcare entities, it is necessary to amend legislative acts in the field of healthcare and compulsory social health insurance as part of the draft new Code.

In accordance with the Message of the President of the Republic of Kazakhstan dated January 27, 2017 "Third Modernization of Kazakhstan: Global Competitiveness", one of the priority areas for the development of the Republic of Kazakhstan is accelerated technological modernization with widespread digitalization and automation of all industries.

To ensure transparency in the procurement of medicines, it is necessary to convert the procurement into electronic format.

In addition, a number of norms are proposed aimed at regulating the activities of the Single Distributor in order to transform it regarding logistics issues, which in general will ensure stability and eliminate unnecessary movement of medicines between regions. In addition, one of the basic principles of the work of the Unified Distributor should be the principle of uninterrupted medicine supply, the main purpose of which is the timely and guaranteed receipt of medicines by patients.

Also, the draft Code is intended to address a number of existing legal gaps. Currently, there is no clear regulation of the issues of providing patients with orphan medicines at both the outpatient and inpatient levels, due to the lack of clear criteria for classifying nosologies as orphan diseases. At the moment, the competence of the authorized body does not have a function to approve the criteria for classifying medicines as orphan medicines. At the same time, as part of the registration of medicines on the EAEU common market, the same medicine in one country may have a different status depending on the criteria for determining orphan diseases and their treatment. In this regard, it is necessary to include a separate chapter on the regulation of orphan diseases and provide for the competence of the authorized body to determine the criteria for classifying certain diseases as orphan diseases, as well as approving the list of medicine for these diseases.

V. Improving personnel policies in the health system

The main direction of improving the personnel policy of the health care system in the framework of the implementation of the State Densaulyk program for 2016-2019 is to provide the health care system with competitive specialists who are able to provide quality services in the field of public health in the Republic of Kazakhstan and to meet existing and new challenges for the health care system.

To overcome the existing problem of insufficient efficiency and accessibility of human resources for health care, it is necessary to introduce the best practices in the field of personnel policy in the healthcare system.

In this regard, the new version of the Code must, first of all, review the rights and obligations of medical and pharmaceutical workers. The main emphasis should be placed on increasing the responsibility of medical personnel for the quality and humanity of medical care provided to patients, and the regulation of restrictions placed on medical workers in carrying out professional activities.

Strengthening the status of medical workers should be accompanied by improved incentive mechanisms, including social protection measures and support measures for health workers, as well as wages for health workers.

It is proposed to improve the accounting and planning procedures for health personnel through maintaining a professional register of medical workers, strengthening the role of local executive bodies in forecasting and planning the needs of medical personnel. The provision of regions with medical personnel will be carried out in compliance with the standard of provision of the region with medical workers and will cover the assistance provided by the guaranteed volume of free medical care. The security standard will be fixed by order of the authorized body. approved by the authorized body.

Improvement of the sectoral qualifications system should be carried out by determining the conditions for the development of its main components (ORC, professional standards, qualification characteristics and the nomenclature of specialties, etc.), determining the coordinating body in the field of qualifications, and introducing licensing of medical workers.

To improve the system of continuous professional development of medical workers, the introduction of a funded system (Professional Development Units) is required, which ensures that the achievements of healthcare professionals in the field of professional development are considered. The main tool for recording these achievements should also be the introduction of an electronic portfolio for each specialist within the framework of the Professional Register of Health Workers.

In order to increase the social responsibility of employers for medical workers and improve the quality of services, it should be foreseen for the prospects for implementation by the authorized body as imputed professional liability insurance of medical workers and insurance entities with the participation of the insurance market since 2022.

To do this, the new Code should distinguish between:

- criteria for determining medical error;

- evidence of medical error;

- establishing the guilt of a medical professional.

It is necessary to develop the practice of voluntary professional liability insurance of medical workers and healthcare subjects, on the basis of which a register of detailed statistics of cases of harm to life and health of citizens as a result of a medical error should be created to establish adequate insurance rates and assess possible losses.

It is also proposed to reflect in the Code the strengthening role of professional associations of medical workers and SROs, including in matters of professional certification, continuous professional development.

All this will improve the efficiency of human resources for health and the availability of high-quality medical care for the population of the Republic of Kazakhstan.

VI. E-health development

As noted in the Address of the President of the Republic of Kazakhstan N. Nazarbayev to the people of Kazakhstan dated January 10, 2018, digital data and digital processes daily revolutionize all spheres of human activity, transforming not only the usual methods of exchanging information, but also directly business processes and even whole industry. The task of the state in the conditions of the fourth industrial revolution (Industry 4.0) is to regulate, create an enabling environment for development and timely respond to the challenges associated with the digitalization of all sectors of the economy, including healthcare.

International surveys demonstrate that expanding the use of ICTs in healthcare can help provide better care, reduce medical errors, and strengthen administration. E-health tools are seen as medical technologies that can influence the fundamental characteristics of health: efficiency, accessibility, safety, quality, equity and sustainability. At the same time, in the implementation of such projects, states face a significant number of difficulties, including primarily the lack of readiness of the legislation and regulatory framework. It is not enough to develop or acquire an information system, a holistic view of the planned benefits and the required changes in organizational processes, structures, functions, standards and legislation, as well as considering the specifics of human resources, training issues, cost recovery and cultural traditions of people who will use e-health technologies, is required. Ignoring any of these factors can be a brake on the development of initiatives.

In recent years, a number of projects have been implemented in the international space that significantly expand the scope of ICT in healthcare, including the introduction of augmented reality technologies, mobile technologies, etc. The widespread penetration of information technology and related opportunities generates a change in the existing paradigm of the relationship between the doctor and the patient, transferring them from the paternalistic model (guardian-ward) to the model of joint decision making. Moreover, ICTs can change the traditional perception of the availability of medical services, making the point of care not a hospital or clinic, but the patient himself, regardless of his physical location.

The digitalization strategy currently being implemented provides for a change in the role of all participants in the care process, including more active patient involvement. At the national level, services and mechanisms for integrating medical care should be implemented through the integration of information flows, data processing tools through Big Data technologies, etc.

The implementation of all these technological changes in Kazakhstan's healthcare is only a matter of time, and one of the key barriers to change may be the lack of readiness of the legislative and regulatory framework. Already now, as a pilot project on paperless medical documentation is being implemented, there are acute questions of regulating access to digital data on the health status of patients and the medical care provided to them, responsibility for the correctness and completeness of data entry. Thus, the current version of the code does not provide legislative support even for short-term digitalization plans for healthcare.

The new Code will introduce a number of new concepts that are important for the legislative regulation of e-health, such as: medical data, electronic health passport, paperless hospital, medical information system, mobile health, smart contract in the field of e-health, patient's personal account and other.

Based on the planned full digitalization of medical data, a new vision of the concept of medical confidentiality will be proposed, closely integrated with the regulation of the access rights of medical workers and the patient to personalized health information about the medical care provided. In addition, considering the rejection of paper documentation, it is necessary to consolidate the presumption of patients' consent to the collection and processing of personal medical data in digital format. The legitimacy of the use of electronic medical documents and electronic data will be consolidated.
The provisions regarding the liability of providers of medical services, both organizations and medical personnel, for timely, reliable and complete data entry will be significantly expanded. The current version of the Code does not adequately reflect the legislative norms regarding telemedicine technologies, which are one of the most important tools for ensuring universal coverage of medical services. It is necessary to provide for a significant expansion of the range of applications of telemedicine, moving from the outdated concept of interaction "doctor-doctor" to the concept of "patient-mobile device-doctor". Given the introduction of technology and the processing of big data, appropriate provisions should be provided that describe the legitimacy of their use in healthcare, including prevention, timely and high-quality diagnosis, the optimal choice of treatment and rehabilitation measures.

The doctor's ability to conduct remote consultations, disease management through the introduction of mobile applications will be consolidated. Also, the status of telemedicine consultations will be determined, which will be equivalent to a personal reception.

Certain provisions in the new Code will be devoted to the use of both personal and depersonalized medical data for the purposes of scientific research, determining the policies and strategies of the healthcare system, and making managerial decisions.

In order to ensure the safety and security of data, as well as to ensure the integration of medical data around the patient, points will be added on the need for the widespread implementation of medical information systems and standards for their certification.

VII. Transformation of the Joint Commission on the Quality of Medical Services at the MoH into an independent non-profit legal entity

In modern conditions, the question of the application of other than state types and forms of regulation of economic sectors, in particular in the healthcare, is relevant. Historically, in Kazakhstan, most of the regulatory functions are carried out by the state, which is manifested through the creation of a regulatory framework for the regulation of legal relations.

Currently, the Ministry of Health of the Republic of Kazakhstan is working to reduce administrative barriers and introduce effective and flexible regulations in the healthcare sector. To achieve this goal, it seems justified to introduce a mechanism of interaction between the state, business and society, based on a combination of efforts and a balance of interests of each side.

In accordance with the 82nd step of the Nation's Plan - 100 steps to implement the five institutional reforms of the Head of State in order to introduce advanced standards of medical care, the Joint Commission for the Quality of Medical Services under the Ministry of Health has been created, the activity of which is aimed at developing recommendations for improving clinical protocols, standards of medical education , drug provision, standards of quality management and accessibility of healthcare services .

For the further implementation of the goal of the Plan of the Nation 100 steps to implement the five institutional reforms of the Head of State, the need has ripened for the introduction of a new model for managing the healthcare sector, which, along with state regulation, requires the existence of public administration. This model will be implemented by creating the Joint Commission for the Quality of Medical Services (hereinafter – "**the JCQ**"), in the form of an independent legal entity. This will make decisions by the professional community in consensus with the state.

This model involves the transfer of a number of state functions of the JCQ. The JCQ is supposed to transfer the following state functions:

- approval of standards and regulations in the field of health;

- approval of the national dosage form;

- determination of the procedure for accreditation in the field of healthcare;

- accreditation of organizations assessing professional preparedness and confirming the qualifications of specialists in the field of healthcare.

As such, it is proposed to create the JCQ in the form of a non-profit organization whose purpose is to ensure favorable conditions and quality in the provision of medical and pharmaceutical services, as well as self-regulation of the healthcare industry. The legal status of a non-profit organization will be in the form of a legal entity - a republican public association, the founders of which will be public associations (associations of individuals) and associations (associations of legal entities) that meet certain criteria.

The responsibilities of the JCQ are:

1. Improving clinical protocols, standards for the organization of medical care, standards for medical education, drug provision, standards for a quality control system and accessibility of health services;

2. Providing the population with safe, clinically and cost-effective, high-quality and affordable medical services, and medical technologies (medicines, medical devices and medical equipment, etc.);

3. Ensuring the quality of medical care, scientific and educational activities in the field of healthcare, drug and material support, human resource management, development of healthcare infrastructure.

The founders of JCQ are public associations (associations of individuals) and associations (associations of legal entities) that meet certain criteria.

Criteria for public associations:

- belonging to a medical or pharmaceutical specialty;

- members of a public association are at least 25% of the number of all specialists in the country in a given specialty.

The criterion for associations of legal entities:

- membership in healthcare organizations;

- members of a union of legal entities are representatives of at least 5 regions.

Explanatory note:

- the criterion for the number of specialists was developed considering the average statistical indicator of the membership of existing public associations in the field of healthcare and international experience.

Currently, there are public associations with the number of 41 out of 56 (73.2%) medical and pharmaceutical specialties, which members are from 5 to 50% of medical personnel by specialty.

Members of the JCQ are public associations (associations of individuals) and associations (associations of legal entities) that meet the similar criteria of the founders.

Management bodies

1. The management bodies of the JCC are:

1) general meeting - the highest management body;

2) the presidium - the management body;

3) the executive body - the one-person;

4) the auditor - the control body;

5) a specialized body.

The structure and staff of the JCQ

The supreme managing body of the JCQ is the general meeting, whose main competence includes the approval of the charter of the JCQ, the election and dismissal of members of the presidium, the auditor.

The Presidium of the JCQ is a collegial managing body, consists of 15 members and is headed by its chairman. The Presidium is formed by:

- 3 representatives from the Ministry of Health of the Republic of Kazakhstan;

- 3 representatives from the Social Health Insurance Fund;

- 6 representatives from members;

- 3 independent members.

Specialized body

In order to monitor the healthcare industry, a specialized body of the JCQ will be created. The specialized body of the JCQ is the body that monitors compliance with the requirements approved by the JCQ.

The executive body is represented by the chairman of the JCQ, who is elected by the decision of the JCQ Presidium.

VIII. Improving Public Health Control and Oversight

The creation of a new sphere of public health by integrating the sphere of sanitary and epidemiological welfare of the population, technical regulation and quality control of the provision of medical services requires a review of approaches to the issues of control and supervision in this area.

In order to improve the control of supervision in the field of public health and reduce administrative barriers, it became necessary to regulate the issues of preventive control and supervision in the field of public health with and without visits to objects (subjects) subject to control and supervision, as well as the validity period of permits.

The law draft defines clear boundaries for public health control and supervision.

Specific types of preventive control are determined without visiting the objects (subjects) to be controlled, such as monitoring notifications, results of industrial sanitary and epidemiological control, sanitary and epidemiological audit, notifications in the field of public health, desk monitoring of product safety, sanitary and epidemiological monitoring, monitoring of infectious and noncommunicable diseases, as well as monitoring the results of the examination of the quality of medical services conducted by the Foundation social health insurance, and monitoring the effectiveness of patient support services and internal control.

In this connection, there was a need to regulate their definition, the order of conduct with the obligatory indication of the goals, tools, methods of conduct, a list of subjects, the frequency of conduct, the method of accounting for preventive control and supervision without visiting the subject (object) of control and supervision and, accordingly, the competence of the state body in public health, according to them.

Since their results in the future can serve as the basis for the selection of subjects (objects) of control and supervision for preventive control and supervision with a visit to the subject (object) of control and supervision.

Today, the Social Health Insurance Fund (hereinafter – "**the Fund**") monitors the performance by health entities of contractual obligations regarding the quality and volume of medical care provided to consumers of medical services.

In this regard, it is necessary for the Fund to consolidate the competence to conduct an examination of the quality and scope of medical services in information systems in the field of healthcare; issuing to health organizations conclusions on compliance with the provision of high-tech medical services.

In turn, the Committee of Quality and Safety Control of the Ministry of Health of the Republic of Kazakhstan and its territorial departments will monitor the examination of the quality and volume of medical services, the validity of issuing conclusions to health organizations on compliance with the provision of high-tech medical services.

Technical regulation. The draft law has been developed to implement the requirements of supranational legislation of the EAEU Member States in the field of technical regulation. Based on the paragraph of the second paragraph of Article 53 of the Treaty on the Eurasian Economic Union of May 29, 2014, committed in the city of Astana, at the national level, it is necessary to determine the principles and approaches for implementing state control and supervision over compliance with technical regulations.

The development of the draft law is also necessary to improve the system of state control and supervision to comply with the requirements of technical regulations and ensure the reliability of conformity assessment procedures, in order to create conditions for fair competition, production and circulation of safe products on the territory of the Republic of Kazakhstan.

Ensuring the safety of products (goods) subject to sanitary and epidemiological control is one of the main conditions for ensuring the national security of the country and the formation of a strong state, its successful long-term development and economic growth and is becoming particularly relevant in the context of integration processes in the Eurasian Economic Union (hereinafter – "**the EAEU**") and the World Trade Organization (hereinafter – "**the WTO**").

International approaches to food safety as an integral part are reflected in the Code of Alimentarius standards, EU directives, in the Global Plan of Action for the Prevention and Control of NCDs for 2013-2020, in the WHO Plan of Action for Food and Nutrition for 2015-2020 years.

Regulation in the field of safety and quality of products (goods) should include the following aspects:

- ensuring a high level of health protection;

- high quality, transparency and independent scientific advice on risk assessment, risk management and risk-based communications;

- application of the precautionary principle and the adoption of temporary measures if an unacceptable level of health risk has been identified, or if a full risk assessment cannot be performed;

- consumer rights to access accurate and sufficient information;

- ensuring traceability of food products and return (withdrawal) procedures in case of non-compliance;

- clear provisions establishing the responsibility of manufacturers and processors for product safety;

- an obligation to ensure that only safe and properly labeled goods are presented on the market;

- fulfillment of the country's international obligations regarding trade.

Currently, control over the safety of products subject to sanitary and epidemiological control (supervision) is carried out in the form of monitoring the safety of products through sampling and its sanitary and epidemiological expertise, as well as cameral control, which allows controlling the safety of products without additional burden on the business, considering the balance of interests of the state, business entities and consumers.

According to the results of the last 3 years, the number of non-conforming products subject to sanitary and epidemiological control is gradually decreasing, so in 2015 -30.1%, in 2016 -14.4%, in 2017 - 10.3% (including food products in 2015 - 26%, in 2016 - 12.2%, in 2017 - 8.3%).

The main section (60-70%) of non-conforming products (goods) in general, sold on the country's market, are imported products.

Considering that products (goods), with the exception of toys, are imported into the country under the condition of conditional release, an effective mechanism for identifying products (goods) that do not meet the requirements of regulatory legal acts in the field of public health, hygiene standards and technical

regulations is the monitoring of product safety carried out in the form of preventive control and supervision with a visit to the subject (object) of control and supervision.

The draft law proposes carrying out preventive control and supervision with a visit to the subject (object) in order to monitor product safety without notifying the subject of control about the upcoming selection of products in order to avoid concealment of inappropriate products, including expired ones or products that are sold without documentation of conformity.

It is necessary to regulate the timing of preventive control and supervision for microenterprises, considering the time spent on laboratory examination.

Further improvement of the legislation is required to take measures in case of violations of product labeling in the absence of shelf life and storage conditions for food products that require special storage conditions, lack of information on the composition of the product, its nutritional and energy value, containing prohibited food additives, preservatives, GMOs. Human consumption of such products can lead to long-term illnesses, allergic reactions, obesity, diabetes mellitus and other noncommunicable diseases.

So, the issue of refusal of registration by territorial divisions of the Committee of Legal Statistics and special records of the General Prosecutor's Office of the Republic of Kazakhstan of unscheduled inspections on the facts of detecting violations of labeling of food products remains relevant. At the same time, the goal of adopting all technical regulations is to protect human life and (or) human health and prevent actions that mislead consumers. The inability to conduct unscheduled inspections of violations of labeling requirements contributes to the presence of food products on the country's consumer market, the labeling of which

In accordance with subparagraph 2) of paragraph 1 of the Code of the Republic of Kazakhstan dated 26 December 2017 "On customs regulation in the Republic of Kazakhstan", it is stipulated that goods are considered conditionally released in respect of which a restriction applies to compliance with prohibitions and restrictions in accordance with the Treaty of the Union and (or) the legislation of the Republic of Kazakhstan can be confirmed after the release of goods.

At the same time, in practice, as the results of cameral control show, the above requirements are not always observed by participants in foreign economic activity.

Thus, according to the results of monitoring the safety of products carried out through desk control aimed at monitoring the import of products into the country and their passage through the procedures for confirming compliance (certification and declaration) for 2017, the volume of imported and sold products that do not meet the safety requirements of products, only 48%.

Accordingly, products that do not pass the conformity assessment are sold on the country's markets, which is the reason to believe that these products are potentially dangerous since participants in foreign economic activity evade the procedure for assessing the conformity of products because their products do not meet safety requirements.

According to the results of cameral control, in most cases when identifying participants in foreign economic activity who are evading the procedure for assessing product conformity, goods are not available in warehouses, that is, sold. In addition, the size of administrative fines does not correspond to the value of imported goods. Considering that the presence of illegal import of goods in the Republic of Kazakhstan is one of the most acute problems of a national scale that has a negative impact on the life and health of citizens, we believe that cameral control is an effective tool to ensure product safety, including protecting the life and health of consumers.

Cameral control will allow tracking goods during customs clearance of goods in the condition of conditional release and release into domestic consumption to comply with the requirements established by the EAEU and Kazakhstan acts, at the stage of its implementation. In other words, this control will limit the import and sale of goods that do not meet safety requirements into the country, thereby protecting consumers from potentially dangerous products.

The purpose of creating cameral control is:

protection of life and health of citizens;

exclusion of illegal circulation of goods in the territory of the Republic of Kazakhstan;

improvement of state control (supervision) in the field of public health and in the field of technical regulation;

ensuring product safety.

In this way, the main tasks of creating a cameral control system in the Republic of Kazakhstan are:

- implementation of state control over the circulation of goods, for compliance with safety requirements;

- improvement of procedures and terms for conducting state control (supervision) in relation to participants in foreign economic activity, imported goods in conditional release mode;

- confirmation of the authenticity of goods;

- counteraction to illegal production and circulation of goods;

- creation of equal conditions for business - prevention, restriction and suppression of the activities of unscrupulous participants in foreign economic activity;

- improvement of information interaction with national components of customs and tax administration in order to track goods during customs clearance online;

- expanding consumer awareness of unfair Participants of Foreign Economic Activity.

Existing information systems do not provide efficient data exchange with other databases of interested state bodies, departments and international organizations.

For operational interaction with territorial divisions and adoption of response measures, it is not possible to monitor product safety monitoring online.

The existing system of laboratory control, considering the development of technologies and solving problems to ensure the sanitary and epidemiological well-being of the population, requires constant improvement and retrofitting. One of the issues requiring solution and reducing the effectiveness of control is the length of the period of implementation of new research methods and standards (more than 3 years) with the approval of state authorities and approval by standardization and metrology bodies.

Achieving the above goals in full is impossible by making changes and additions to the current legislation. Proceeding from this, it is necessary to apply new and systemic decisions, with their implementation in the draft Law set forth in the new edition.

Also, the food and environmental aspects of health are essential. These issues are components of public health and can be implemented through intersectoral collaboration. In this regard, the responsibility of other sectors of the economy will be spelt out in the Code by defining the responsibilities and functions of each interested sector of the economy in protecting public health, and a section is also provided for protecting health from environmental factors.

At the same time, taking into account the comments of the Institute of Legislation, the Ministry will finalize and further include a section on protecting health from environmental factors.

Quality control of the medical services provision. It is well known that the quality of medical care does not arise in the control process, but is formed at each stage of the provision of medical services and combines many parameters. Among them are the organization of medical care processes in accordance

with standards in the field of healthcare, the material and technical condition of the medical organization, the personnel structure, their qualifications, work with personnel, standardized approaches to diagnosis and treatment.

Today in Kazakhstan, the problem of the medical services quality is solved mainly through control, which is aimed at identifying defects according to the results of the medical organization, that is, the final result.

Quality control of the medical services provision requires periodic inspections and the application of prompt response measures without initiating administrative proceedings (supervision).

According to this aim, it is proposed that the scope of the provided medical services quality be included in the list of activities of business entities in which supervision is carried out (to supplement Article 139 of the Entrepreneurial Code of the Republic of Kazakhstan with public health).

This measure will allow during the implementation of the audit to apply rapid response measures and restrictive measures without initiating administrative proceedings.

There is a tendency towards an increase in citizens' appeals for the quality of medical care; in 2017, the number of requests is 5% more than in the previous year. At the same time, in a number of cases, the facts of the development of complications or the onset of deaths as a result of medical care are published in the media, on social networks and cause a public outcry among the population. In this connection, the need arose for conducting inspections in a special order, the expected result is an increase in the efficiency of the activities of medical organizations through timely monitoring and supervision.

The purpose of creating a check-in a special order and introducing a supervisory function over the quality of the medical services provided is:

- protection of life and health of citizens;
- improving state control (supervision) over the quality of medical services provided;
- improving the quality of medical services to the population.

It is proposed to classify some health entities (for example, maternity hospitals, infectious hospitals, organizations providing high-tech medical services) as objects of high risk and apply a special procedure for conducting inspections in their respect (add some entities for the provision of medical services in Article 141 of the Entrepreneurial Code of the Republic of Kazakhstan).

When introducing the supervisory function and conducting an audit in a special order, the state control (supervision) body over the quality of the medical services provided will take prompt response measures (administrative penalties and legal restrictive prompt response measures without initiating administrative proceedings).

In order to strengthen preventive control aimed at preventing violations in the provision of medical services, it is proposed to provide for the approval of a clear list of highly significant subjects (objects) subject to medical control, which in turn will give the right to control inspectors in the provision of medical services to make a sudden visit to a medical organization (for example, organizations providing HTMC, obstetric facilities, stroke centers, trauma clinics, emergency medical stations, oncology dispensaries, including when receiving resonant messages from the media, etc.), with the possibility of short-term finding and monitoring processes in order to determine whether the medical organization’s activities comply with health legislation or, if inconsistencies are detected, warn the subject (object) about them and providing recommendations for their elimination, in accordance with the order of visits approved by the authorized body. At the same time, during the visit, the inspector will be prohibited from interfering in the activities of the subject, as well as suspend any activity.

Such a mechanism will not be intended to punish the subject, but to effectively identify inconsistencies in their activities with the requirements of health legislation.

Accordingly, the inspector performs the function of an auditor, which helps to identify non-compliance and is limited only to notification (verbal or written) of the entity of the existing or potential non-compliance

without initiating administrative proceedings or other preventive measures. In case of detection of an obvious fact of a threat of harm to health, an unscheduled check should be appointed in accordance with the grounds and procedure established in the Entrepreneurial Code of the Republic of Kazakhstan.

This system will increase the likelihood of detecting violations of the law in the field of healthcare and ensure transparency in the activities of subjects (objects). In this regard, it is proposed to remove the above objects from the scope of the Entrepreneurial Code.

It is also proposed to withdraw from the scope of the Entrepreneurial Code of the Republic of Kazakhstan an investigation of individual cases (maternal mortality, especially dangerous infections, resonant cases) by analogy with the investigation of accidents in accordance with the Labor Code of the Republic of Kazakhstan.

Investigation of individual cases will be carried out by a commission created on the basis of emergency notice provided by health entities.

At the moment, the state control system in the provision of medical services lacks emergency notification mechanisms in some cases (for example, maternal and child mortality, other causes of deaths when receiving medical care on an outpatient basis, including the use of general anesthesia, with especially dangerous infections, etc.), which would serve as the basis for an operational response.

In this connection, the Ministry of Health of the Republic of Kazakhstan must be empowered with the development and approval of a regulatory legal act governing the submission of extraordinary information (emergency notice) to the Ministry of Health of the Republic of Kazakhstan on cases of infectious diseases, poisoning and fatal situations requiring special control.

In order to increase the efficiency of the activity of the heads of health departments, it is proposed to provide an annual report of the heads of the health department on the results of their activities to the certification commission of the authorized body, including the achievement of target indicators in accordance with the memorandum (similar to the system for evaluating the effectiveness of reporting of the secretaries of central government bodies to the Presidential Administration RK).

In the event of a decrease in performance indicators and (or) failure to achieve the target indicators identified by the reporting results, the certification committee of the authorized body submits to the local executive body the decision on the issue of compliance with the position of the head of the health department.

Based on the results of inspections by the Public Health Protection Committee of the Ministry of Health of the Republic of Kazakhstan, administrative penalties are applied according to their competence in accordance with the Code of the Republic of Kazakhstan "On administrative offenses".

In 2017, 430 administrative cases were initiated for a total amount of 8891.2 thousand tenge, 299 individuals (5197.3 thousand tenge), 87 officials (2321.5 thousand tenge) and 23 legal entities were brought to administrative responsibility (1372.4 thousand tenge).

For 6 months of 2018, 353 administrative cases were initiated for a total of 6,804.2 thousand tenge (6 months of 2017 - 212 cases in the amount of 4,366.3 thousand tenge; 6 months of 2016 - 338 cases in the amount of 7,436.9 tenge).

Today, administrative penalties are more heavily imposed on individuals of control subjects (objects) (doctors and nurses), while officials of control subjects, in accordance with the Code of Administrative Offenses of the Republic of Kazakhstan (chief physician, deputy chief physician), are less responsible, 3 times less, which is reflected in the above statistics. Namely, officials should be fully responsible for violating standards and providing low-quality medical care, as those responsible for organizing the provision of medical care (staffing, logistics, medical equipment, etc.) and creating working conditions for healthcare professionals.

In the current Administrative Code of the Republic of Kazakhstan, there is no administrative responsibility of local public health authorities of oblasts, a city of republican significance and the capital (head of the healthcare institution and his deputies), since in accordance with Articles 9 and 10 of the Code of the Republic of Kazakhstan "On public health and healthcare system", they have authority (rights and obligations) include ensuring the implementation of the legislation of the Republic of Kazakhstan in the field of healthcare, taking measures to improve the quality of medical services, ensuring basic public health organizations, the organization of staffing of public health organizations, to ensure the citizens of the Republic of Kazakhstan, repatriates and foreigners and stateless persons permanently residing in the territory of the Republic of Kazakhstan, medical care and drugs, medical products.

In this regard, it is proposed to provide for the (administrative) responsibility of the heads of the Health Departments for failure to submit or untimely notification / urgent notification of fatal situations requiring special control in cases of mass infectious diseases and poisoning; failure to comply with regulatory legal acts and standards of the Ministry of Health of the Republic of Kazakhstan on a regional scale; failure to achieve key performance indicators.

At the same time, the issue of attracting the heads of local public health administration bodies to the disciplinary body is within the competence of a higher authority represented by the Akimat of the regions, which, in accordance with Article 9 of the Code of the Republic of Kazakhstan "On public health and healthcare system", appoint and dismiss the heads of local authorities public health administration of regions, cities of republican significance and the capital as agreed with the authorized body.

In addition, it is proposed to provide the authority of the Ministry of Health of the Republic of Kazakhstan to suspend the doctor's certificate or the activities of the clinic (department) in cases of gross violations in the field of health.

The norms of legislation in the field of healthcare only provide for the initiation of revocation of a specialist's certificate and (or) a license for medical activity.

Cases of non-provision of medical care and the continuation of the performance of official duties by medical workers who have committed fatal cases for which criminal proceedings have been instituted by the investigating authorities cause resonance both among the population and the media and can be regarded as the inaction of the state body for quality control of medical services. At the same time, law enforcement authorities carry out investigative actions up to 2-3 years.

In this regard, it is proposed to develop an algorithm, rules and procedure for revoking a license and a specialist's certificate with the identification of the person initiating the claim and the authority through which the review will be carried out or impose this function on the state control body with the definition of specific criteria for the prohibition of activities to individuals or healthcare providers.

Alternatives to verifications. One part of the activity in this area is the Institute of Sanitary and Epidemiological Audit, which in 2015 was introduced for the first time in the republic as an alternative to audits. The results of a positive sanitary and epidemiological audit allowed objects of high epidemic importance to be freed from inspections in a special order, which significantly reduced the burden on the business, and the corresponding task set by the head of state was also completed.

In practice, the application of this rule raises questions related to the procedure for releasing objects of high epidemiological significance from inspections conducted in a special order. In this regard, a clear regulation of the basis for exemption based on the audit results with the definition of a criterion for assessing the degree of risk is necessary.

Through this process, a clear regulation of the grounds for exemption from inspections in a special order, the duration of audit reports, as well as the duties of auditors to conduct intermediate control at audited facilities during the period to be released, is proposed to exclude a double interpretation of regulatory legal acts and reduce corruption risks by government bodies, as well as unreasonable release by auditors of objects with high epidemic risk for an unlimited period.

Expertise in the public health field. Issues of support and development of entrepreneurship are one of the main directions of state policy. Attention is focused on the interaction of business entities and the state, including state regulation and support of business, provides general rules on business, business entities, associations of business entities and the conditions for their functioning.

In order to prevent the turnover and delivery of products that do not meet the requirements of the regulatory legal acts, determining the level of qualification of specialists in the field of public health, the activities of laboratories using potentially hazardous chemical and biological substances, the regulation of expertise are regulated.

Investigations. Prevention of infectious and non-infectious diseases as part of the public health sector requires prompt measures, timely sanitary and epidemiological measures in the foci of group infectious, parasitic and non-infectious diseases (poisonings), identification of the causes of their occurrence and localization of the outbreak, and regulation of this issue in the Code, in therefore, the rules on the procedure for the investigation and recording of cases of group infectious and parasitic, occupational diseases poisoning and poisoning will be directly regulated in the Code.

Implementation of confidential audit and creation of a national system of accounting and analysis of medical errors.

The analysis showed that the OECD countries use a system of accounting and analysis of incidents (*this is any deviation from the standard of medical care, which results in harm to the patient*); in case of reporting the incident, there are no punitive measures on the part of the authorities that control the quality of medical care and the law enforcement system. Incident information is kept confidential. Health organizations have introduced a safety culture that motivates workers to report incidents.

By the way, WHO indicates that the fundamental role of this system is to improve patient safety by examining health system errors and making recommendations for improvement.

In this regard, in order to introduce a confidential audit in accordance with international standards in the Republic of Kazakhstan, it is necessary to legislate such concepts and terms as an incident (an event that deviated from the normal work process), confidential audit - a systematic multidisciplinary anonymous investigation of medical error cases - which will be the basis of the National medical error accounting and analysis systems).

As part of the ongoing digitalization of the healthcare system, provide for the introduction of an automated system for recording and analyzing medical errors.

A sustainable improvement in the quality of medical services will also be ensured through the development of accreditation of health care providers for compliance with national standards of quality and safety in the field of healthcare. Today, the accreditation system is on the next branch of development. In order to maintain the sustainability of compliance with accreditation standards, post-accreditation monitoring will be carried out throughout the validity period of the accreditation certificate.

Also, the authorized body will be assigned the competence of accreditation of professional medical associations, healthcare entities accrediting medical organizations, as well as assessing professional preparedness and confirming the qualifications of specialists in the field of health.

Establishment of the Chamber of Independent Experts in the health care field with branches involved in assessing the quality of medical care.

One of the tools for managing the quality of medical care is the regulatory support of the activities of subjects of the health care system. Assessment of the level of quality of medical care provided by subjects of the healthcare system is carried out through the Institute of Independent Medical Expertise.

Along with the improvement of certain indicators of the health system of the Republic of Kazakhstan, the professional medical community is alarmed by the growth of criminal cases against doctors.

The need to decriminalize legislation and the current situation in the provision of medical services is justified and is due to the fact that the prestige of the medical profession is devalued and the outflow of medical specialists from the Republic of Kazakhstan is increasing, which in turn will only exacerbate the shortage of doctors and specialists in the country. On the other hand, in the opinion of the medical community, the lack of specialized medical knowledge among law enforcement and judicial officials sometimes entails cases of incorrect interpretation of the medical situation and determination of the degree of guilt of medical workers, which leads to unjustifiably severe punishments of imprisonment of doctors and / or imprisonment their rights to engage in professional activities.

Given the above circumstances, the need has ripened for the establishment of a Chamber of independent experts in the field of health by analogy with the Chamber of forensic experts of the Republic of Kazakhstan, where the basic mechanisms for regulating the activities of independent experts in the field of health will be provided.

The Chamber will be a non-profit, professional, self-financing organization that unites all independent experts in the field of healthcare on the basis of compulsory membership, coordinates the activities of independent experts and complies with the laws of the Republic of Kazakhstan.

The subject of the Chamber's activities will be the coordination and organization of the activities of independent medical experts on the territory of the Republic of Kazakhstan.

The Chamber will introduce the Register of Independent Experts and develop a procedure for their submission, as well as the Chamber will consider all complex and controversial cases of examination.

The creation of the chamber will provide an opportunity to improve and develop the institute of independent medical experts, to protect the social and professional rights of independent experts, as well as improve the quality of medical expertise and the role of independent experts involved in the production of expertise.

Other directions

Management in public health organizations.

In connection with the further efficiency of the medical organization's work related to its break-even activity, improving the quality of medical services, increasing the level of the corporate system of the medical organization, management and achieving key performance indicators for managers, it is necessary at the legislative level to provide for the term of the employment contract of the head of the medical organization to be no more 3 years with the possibility of its extension.

In this connection, the new draft Health Code proposes the following:

to establish the conclusion of an employment contract with the head of the medical organization for a period of not more than three years with the possibility of its extension in agreement with the authorized body based on the results of achieving key performance indicators of managers, with the exception of the heads of medical organizations, labor relations of which are regulated by the laws of the Republic of Kazakhstan "On special state bodies of the Republic of Kazakhstan" and "On military service and the status of military personnel".

At the same time, this direction will also be reflected in the Labour Code of the Republic of Kazakhstan.

Corporate management in public health organizations:

Improving corporate management will facilitate the efficient allocation of public resources in the healthcare sector, and ensure transparency and accountability of management bodies in accordance with the OECD guidelines for corporate management in public enterprises. This approach in the field of healthcare will help to improve the quality of medical services and promote investor confidence and attract long-term capital.

In this regard, the new draft Health Code proposes to provide competence to the authorized body for:

- the development of standard forms of corporate governance documents for state organizations with a supervisory board and the procedure for their approval (standard code of business ethics, standard personnel policy, model regulation on information policy, standard information on secrets);
- development and approval of rules for evaluating the corporate governance of state-owned enterprises in the field of healthcare.

Mechanisms conducive to the development of corporate governance in healthcare organizations, such as the development of model corporate documents (model code of business ethics, model personnel policy, model regulation on information policy, standard information on secrets) and development, approval of rules for evaluating corporate governance of state enterprises in the field of health care. The implementation of these documents will contribute to the improvement of corporate governance, the efficient allocation of public resources in the healthcare sector, and will ensure transparency and accountability of government bodies in accordance with the OECD guidelines for corporate governance in public enterprises.

National Healthcare Accounts.

The OECD experts in the report "Review of National Health Accounts" recommended the introduction of an internationally recognized tool for National Health Accounts (hereinafter – "**the NHAs**"), which is used in more than 190 countries. According to their purpose, the NHAs allows you to quickly respond to the requirements of health policy and provide information of such degree of detail that is necessary for good macroeconomic planning and assessment of the success of policy implementation.

The NHA is a statistical tool that provides a systematic measurement of the flow of all cash (from both public and private sources) in the health care system by tracking revenues from financing schemes up to the final point of use by type of service and characteristics of the ultimate beneficiary.

The NHAs of the Republic of Kazakhstan use the statistical information of the National Bank of the Republic of Kazakhstan on the costs and administrative costs of private medical insurers to formulate the total costs of voluntary medical insurance.

The NHAs are built on the basis of the "System of Health Accounts" methodology compiled by joint efforts of the OECD, WHO and the European Statistical Organization (Eurostat). NHA allows you to collect and process information about the sources and use of funds of the health care system in the country and compare it with other countries.

As sources of information in the formation of the NHA, the data generated and published by the Ministry of Finance of the Republic of Kazakhstan, the Ministry of Health of the Republic of Kazakhstan, the Committee on Statistics of the Ministry of National Economy of the Republic of Kazakhstan, as well as information from the official website of the National Bank of the Republic of Kazakhstan from the "Consolidated report on insurance payments on insurance (reinsurance) organizations of the Republic of Kazakhstan" and from the "Consolidated report on insurance premiums for insurance (reinsurance) organizations Republic of Kazakhstan", from the database "Creditors reporting system" of the Development Assistance Committee of the Organization for Economic Cooperation and Development. The NHA formation does not imply the need for information on the accounts of the Fund.

When compiling national health accounts, additional responsibilities will not be assigned to business entities in terms of providing the necessary information.

In this regard, it is proposed to legislatively define the concept of the NHA, the purpose of its application and to regulate the process of its formation.

The implementation of the NHA will allow for regular, comprehensive and consistent monitoring of financial flows in the country's healthcare system.

Duty and responsibility of local executive bodies of oblasts, a city of republican significance and the capital on the implementation of the state policy in the healthcare field.

It is proposed in the new Health Code to establish the obligation and responsibility of local executive bodies of regions, the city of republican significance and the capital of the following content:

Local executive bodies of regions, cities of republican significance and the capital are required to:

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

2) ensure the implementation of the decision of the authorized body in the field of health;

3) carry out the implementation of activities in the field of health;

4) to appoint and dismiss the heads of state healthcare organizations in agreement with the authorized body.

The authorized body has the right to make a submission to the local executive bodies of regions, cities of republican significance and the capital on the appointment and dismissal of heads of state health organizations.

Local executive bodies of oblasts, cities of republican significance and the capital are responsible for failure to fulfill obligations for the implementation of state health policy on the proposal of the authorized body.

Expanding the competence and responsibility of local public health authorities of oblasts, cities of republican significance and the capital.

It is proposed in the new Health Code to expand the competence and responsibility of local public health authorities of oblasts, cities of republican significance and the capital, namely:

1) ensure the implementation of the decision of the authorized body in the field of health;

2) submit a quarterly report to the authorized body on the implementation of the state program for the development of health care, regional programs, the main quantitative and qualitative indicators of health care;

3) make proposals to the authorized body to improve the performance of the health care system within the relevant administrative-territorial unit, including the development of primary health care, the protection of motherhood and childhood, and the implementation of the program for socially significant diseases;

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

The first heads of local public healthcare authorities of regions, cities of republican significance and the capital are personally responsible for the performance of the official powers provided for in this article in accordance with the Code of the Republic of Kazakhstan "On administrative offenses".

In case of non-fulfillment or improper fulfillment of the functions and powers by the first heads of local bodies of state administration of health care in regions, cities of republican significance and the capital, the authorized body is entitled to initiate the issue of the further occupation of a public post by these persons.

The international cooperation

International cooperation is an important factor to ensure a modern approach to achieving the goals and solving problems of the healthcare sector.

Based on relations of good neighborliness with the states of cooperation, in the framework of international cooperation in the field of healthcare, in the course of international integration, the Ministry adheres to the position of protecting national interests, full participation in international agreements, associations in the field of health, initiative to build a common global healthcare space, seek consent, coincide interests and create, on this basis, a system of bilateral and multilateral partnerships.

Collaboration with WHO, UNAIDS, UNICEF, OECD is an integral part of the comprehensive development of the national health system and is aimed at supporting it in accordance with global health priorities.

The development of cooperation and interaction among the CIS member states in the field of healthcare will continue in the implementation of the Strategy "Health of the CIS member states population", which is fully consistent with the WHO "Health 2020" policy.

One of the priorities within the framework of the Eurasian Economic Union is to ensure the full functioning of the single market for medicines and medical devices, the development of digitalization in the field of healthcare within the EAEU, the provision of medical assistance to migrant workers and members of their families in the EAEU member states, the functioning of domestic markets without barriers, obstacles and restrictions; implementation of an agreed policy on sanitary measures.

Joint activities and mutual support within the framework of the SCO, CSTO and other international organizations will continue.

The development of relations in the field of health with the states of Central Asia and the South Caucasus will focus on enhancing mutually beneficial cooperation on the development of medical and educational tourism, promoting the expansion of the export potential of domestic pharmaceutical manufacturers, exchanging information in the field of sanitary and epidemiological welfare, etc.

The Ministry attaches great importance to strengthening cooperation in the field of healthcare with the Russian Federation, the Republic of Belarus and is aimed at their activation in introducing digital technologies in the healthcare sector, implementing joint research projects in the field of biomedicine, and partnerships in the pharmaceutical field.

3. The objectives of the draft law

The aim of the draft Code is to improve and develop the current legislation in the field of healthcare, in particular the development of the public health system, the improvement of medical education and science, e-health in the Republic of Kazakhstan, ensuring the quality and effectiveness of medical care.

The current Code laid the initial stages of the development of the health system for the country to enter the 50 most competitive countries in the world. The adoption of the new draft Code is due to the need to develop and implement a long-term, effective and sustainable model of health care as one of the factors that make the republic one of the 30 most competitive countries in the world.

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The new version of the draft Code will be aimed at laying the foundation for accelerated development of the industry to ensure that the level of healthcare is consistent with the level of the OECD countries and to improving the health of the nation, increasing the life expectancy of the population and the development of medical technologies, reorienting modern healthcare to disease prevention, and not to expensive inpatient treatment, and strengthening public health management, promoting healthy lifestyles and strengthening the reproductive health of youth, the transition from small effective and costly for the state

medical examination for the management of major chronic diseases using modern digital technologies, personalized medicine, issues of digitalization.

Also, the purpose of the adoption of the Code is to reduce the reference, blanket norms and other shortcomings of the current Code, which distort the meaning and content of the legal act.

4. The subject of the draft law regulation

The subject of the draft Code regulation is public relations in the healthcare field.

5. The structure and content of the draft law

The draft Code consists of 7 sections, 23 chapters:

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Chapter 16. Educational activity

Chapter 17. Scientific activity

SECTION 5. PHARMACEUTICAL ACTIVITY AND HANDLING OF MEDICINES AND MEDICAL PRODUCTS

Chapter 18. Pharmaceutical activities and circulation of medicines and medical devices

Chapter 19. Circulation of medicines

Chapter 20. Circulation of medical devices

SECTION 6. PERSONNEL POLICY IN THE HEALTHCARE FIELD

Chapter 21. Human resources in health care

Chapter 22. Rights, duties and restrictions of medical and pharmaceutical workers

Chapter 23. Status of a medical worker and social guarantees

SECTION 7. FINAL AND TRANSITIONAL PROVISIONS

6. The results of the legal monitoring of legislative acts in the relevant field

The results of legal monitoring of legislative acts on these issues conducted by authorized bodies are considered in this concept.

7. Estimated legal and socio-economic consequences in case of adoption of the draft law

The adoption of the draft Code will entail favorable legal and socio-economic consequences, namely:

- ensuring equal rights of citizens to receive safe, effective and high-quality medical care, as well as ensuring the availability of medical care;

- the joint responsibility of the population, the state and employers for the preservation and strengthening of individual and public health;

- the priority of the preventive orientation in the activities of the health system;

- attribution of public health, safety, efficacy and quality of medicines to the factors of ensuring national security;

- ensuring the availability of safe, effective and high-quality medicines and medical products;

- attracting new investments in the healthcare sector and the development of public-private partnerships.

8. The need for simultaneous (subsequent) bringing other legislative acts in line with the draft law being developed

The development of the draft Code will require the statement on the loss of the Code of the Republic of Kazakhstan "On public health and healthcare system" and the laws of the Republic of Kazakhstan dated October 14, 2003 "On the prevention of iodine deficiency diseases" and dated April 7, 1995 "On the compulsory treatment of patients with alcoholism, drug addiction and substance abuse" at the same time, the norms of the above legislative acts will be integrated and systematized in the draft new Code.

In this regard, after the adoption of the new Code, all by-laws and normative legal acts will be revised, including the list of medical contraindications available to patients with alcoholism, drug addiction and substance abuse, for which referral to drug treatment organizations for compulsory treatment is not applied.

As for the consideration of the issue of changing the source of financing the activities of the Centres for Temporary Adaptation and Detoxification from the republican to the local budget, this issue is considered in the framework of optimization of the GVFMC and the introduction of the CSMI.

In addition, proposals for organizing and referring to compulsory treatment will be considered in the draft new Code.

Also, the development of the draft Code will require amendments and additions to some legislative acts, including: Criminal, Entrepreneurial, Labour, Budget Codes and the Code "On administrative offenses", Laws of the Republic of Kazakhstan "On state property", "On education", "On science", "On self-regulation", "On non-profit organizations", "On mandatory social health insurance", "On permits and notifications", "On public-private partnerships", "On informatization", "On personal data and their protection" and "On tourist activity in the Republic of Kazakhstan".

9. Settlement of the subject of the draft law by other regulatory legal acts

The Code of the Republic of Kazakhstan "On public health and healthcare system" and the laws of the Republic of Kazakhstan dated 14 October 2003 "On the prevention of iodine deficiency diseases" and dated April 7, 1995 "On the compulsory treatment of patients with alcoholism, drug addiction and substance abuse".

10. Availability of international experience on the issue under consideration

Public health protection

So, in Europe, there is a National Integrated Strategy / Action Plan to combat the NCDs aimed at measures to reduce the demand for tobacco products, alcohol abuse, and unhealthy diet. In addition, in the fight against the NCDs, great importance is attached to educating the population on a healthy lifestyle, as well as conducting large-scale campaigns to familiarize the population with physical activity.

In the UK, since 2017, a ban has been introduced on the advertising of "harmful" foods high in salt, sugar and trans fats in the daytime. In Europe, labeling on packages of products containing substances harmful to health is a prerequisite for food producers. Since 2010, Finland introduced a tax on sweets and alcohol, as well as a ban on the import of pickles, which led to a decrease in the incidence of the NCDs by 80% and an extension of the life expectancy of the Finns by 10 years compared to the 1980s. In Canada, mandatory flour fortification since 2010 has reduced the birth of children with diseases of the nervous system by 2 times.

Show one's appreciation to interagency cooperation in Finland, an increase in the physical activity of the population brings about $ 5.5 billion to the healthcare system every year. The strengthened work of youth health centers in Estonia has contributed to reducing the prevalence of HIV among adolescents from 43.6% to 1.8% over 5 years (from 2000 - 2005), the number of teenage abortions has decreased from 33% to 16.8% from 2000- 2013 years The implementation of a youth project in Iceland to combat teenage deviant behavior has reduced alcohol consumption by adolescents from 42% (1998) to 5% (2016), and drug use at least once in a lifetime from 17% to 7%.

In Canada, Australia and the United Kingdom, an increase in excise taxes on tobacco products to 80% over the past 10 years has led to a 4-fold decrease in NCDs. In Australia, thanks to large-scale media campaigns over 10 years, smoking prevalence among the population has declined from 23.6% to 17.3%. And in the USA in the states of California, Mississippi, West Virginia there is 100% compliance with the vaccination schedule.

Organization of medical care providing

According to the international experience of the countries, the strategic partnership allowed to train and develop leaders in many areas of medicine, improve clinical experience, strengthen the personnel potential of these countries, carry out institutional reforms in specific areas, stimulated the development of science and allowed researchers to receive international grants. For example, the Cleveland and Abu Dhabi Clinic (Cleveland Clinic Abu Dhabi) was created on the basis of a 2006 agreement between the Mubadala Development Company and the Cleveland Clinic (USA) in support of the Abu Dhabi state program "Economic Vision 2030" to achieve the world-class healthcare sector.

The international experience of strategic partnerships between medical education organizations can also be traced to the example of Singapore. In order to define the country as a biomedical center (hub) of Asia, a medical school of postgraduate education was created together with Duke University (Duke-NUS medical school) to obtain the highly qualified medical leaders needed to support the country initiative in the field of biomedical sciences. After significant progress, on June 2, 2016 in Singapore, further expansion of this cooperation was confirmed by signing the third agreement. Duke-NUS School of Medicine is part of the National University of Singapore system but is unique in that it is controlled by a Board of Governors, including a representative from Duke University, who has the right to veto any decision made by the academic board.

The world experience shows that only in the conditions of integration of science, practice and education is it possible to create an effective environment for obtaining modern knowledge and training a competitive doctor.

One of the main conditions for the functioning of a medical school (university) in developed countries is the presence of a university clinic - the necessary infrastructure for clinical training.

In France, university hospital centers are medical organizations that are part of the university or are an independent organization associated with the university by any agreement. CHU - regional state centers. They form a single network across the country, uniting 32 institutions. On average, there is one university hospital center for each region of the country. Part of the staff of university hospital centers in both medical staff and teachers, that is, working for two organizations and receiving double wages. The unified network of university clinical centers provides a third of hospitalizations in state medical institutions of the country and the whole range of medical services in the field of the emergency ambulance, home care, primary medical care for all types of diseases. Funding for CHU is provided by the state, at the expense of social insurance funds, by charitable organizations.

University clinics in Germany are among the oldest in the world. The first university clinics in the country arose in the 18th century. Currently, there are about 40 university clinics in Germany, which are located in all federal states, in almost all regions of the country. Each year, Germany's university clinics provide inpatient services to around 1.7 million patients. At the same time, very complex or complex types of medical care are mostly provided in university clinics. University hospitals in Germany are financed, as a rule, from three sources: from the local budget, the federal government and scientific organizations, and special funds.

University hospitals in the UK (University Hospitals or Teaching Hospitals) are part of the National Health Service. The NHS UK hospitals are managed by the Acute Trusts, which ensure the quality of medical services provided to patients and the rational use of allocated funds, as well as determine the development strategy of hospitals. Some Acute Trusts are regional or national centres for the provision of services of a more specialized nature, while others are associated with universities or medical schools and participate in the training of medical personnel. The leading national body assisting young professionals in medical practice at its base is the Association of UK University Hospitals. The Association includes 43 trusts. Moreover, one trust may be responsible for several university clinics and hospitals.

More than a thousand training clinics operate in the United States, 400 leading clinics are members of the Council of Teaching Hospitals and Health Systems (COTH) of the Association of American Medical Universities. The development of mechanisms to ensure the trinity of education, science and practice on the basis of a partnership of academic structures and university clinics in modern conditions led to the creation of academic medical centres (hereinafter – "**the AMCs**"). There are currently 119 AMCs in the United States.

The AMC is a consolidated management structure and a system-wide administrative infrastructure, the values of which cover academic, research and medical components. Integration of these components under a single management allows you to expand the range of services of the organization, increase the potential of medical workers, conduct research with the subsequent implementation of their results in the medical care process. The university clinic is not only the centre of medical innovation and science, but also the basis for the development of the "doctor-scientist-teacher" model. It is expected that, in the processes of education and scientific research, the best practitioners will be motivated to participate, scientists and teachers will have the opportunity to practice and conduct clinical research. This will allow rational use of medical personnel (doctor, teacher, scientist in one person), provide high material and professional motivation of personnel and create a model of scientific and pedagogical career development of medical personnel, which is by far the best standard of professional development in world healthcare.

Research system development in the field of medicine and improving the quality of bioethical expertise

When developing the Code project on single issues, the foreign countries experience in improving the quality of the activities of bioethics commissions on the basis of certification or accreditation was studied and taken into account.

Bioethics commissions are special structures whose task is to conduct independent ethical monitoring of all scientific research with the involvement of a person in order to protect his right to health and life. It functions and develop, interact around the world.

Currently, there are a number of organizations offering a program of international accreditation (or) certification of bioethics commissions. For example, the Association for the Accreditation of Research for Human Research Programs Inc. (hereinafter – "**the AAHRPP**"), Human Research Protection Program (ALION). Both organizations are established in the United States of America. These programs do not exclude any national systems of accreditation / certification of ethics commissions, but they focus on programs for the protection of research on people, as well as organizations that include individuals, committees and units that have responsibilities for protecting the rights of subjects in research held or reviewed by this organization. The scope of these accreditation programs goes far beyond ethics committees. It is based on recognized ethical standards.

These programs can certainly benefit organizations implementing human research protection programs. However, they do not seek to replace national systems for the supervision of public research and the recognition (accreditation / certification) of ethical commissions.

In Canada, a Committee was appointed to monitor the quality of the ethical commissions work. The committee concluded in favor of a unified centralized oversight system, which should be responsible for the accreditation of ethics commissions. The Committee concluded that these functions should be carried out in such a way as to produce continuous improvement in the system.

In Australia, New Zealand and the UK, Belgium, Switzerland, where for some time a control system has been in place, including the accreditation of ethics committees, committees have also been set up to evaluate the work of ethics commissions.

When developing the Code project on single issues, the foreign countries experience in terms of the biobanks activities was studied and taken into account.

Until the 90s of the 20th century, many countries began to create specialized centers (biobanks) with standardized methods for collecting biomaterials, premises for long-term storage of biomaterials, integrated data retrieval systems, and presentation of samples, which allowed the use of biobank materials by medical and research centers to solve research problems.

In the world there are several dozen large biobanks of national scale and several hundred smaller ones. Samples of biological fluids (blood, plasma, saliva, urine) and tissues, as well as DNA, RNA, and other biological substances are stored in biobanks. For example, the National Biobank of Korea (NBK), integrated with 17 regional Korean biobanks, contains more than 525 thousand bio-samples.

Collections of biobanks are used to research diseases, the causes of which are still not completely clear, to create diagnostic and prognostic tests, identify biomarkers of diseases, and also to develop new medicines.

There are banks specializing in rare diseases, twin registers, banks focused on population studies, where they primarily conduct genetic examinations of various population groups to determine the functionality of genes when the most common diseases appear. The Swedish National Biobank Program provides for the conservation of 3-4 million bio-samples obtained annually in routine medical examinations. The British UK Biobank from 2006 to 2010 collected medical data from more than 500 thousand people aged 40 to 69 years.

In many foreign countries, the Bioethics Commission operates.

For example, the Belgian Advisory Committee on Bioethics was formally established on January 15, 1993, in accordance with the Cooperation Agreement between the federal government, the French-speaking community, the Flemish community, the German-speaking community and the Joint Commission for Communities. Its career began in January 1996. The duties of the Committee include the following provision of recommendations on research issues and their applications in the field of biology, medicine and healthcare studied from an ethical, social and legal point of view; informing the public and authorities about existing problems in this area.

The Swiss National Advisory Commission on Biomedical Ethics (Swiss National Advisory Commission on Biomedical Ethics) was established by the Federal Council (Government) in 2001 in accordance with Section 28 of the Federal Law on Medical Assistance. According to the Decree (Regulations of the Federal Council), the Commission's task is to control the development of biomedical research methods, practical methods, formulate advisory opinions on relevant social, scientific and legal issues, inform the public, promote public dialogue on ethical issues; development of recommendations or directives for medical practice, monitoring of gaps in legislation and, if necessary, submission of amendments to them, etc.

At the international level, technical, legal, ethical examination and control of biobanks is carried out by the organization created for these purposes - ISBER (International society for biological and environmental repositories). In addition, there are many other organizations that issue accreditations, permits and certifications that guarantee the proper quality of all processes.

Pharmaceutical activities and medicine product handling

Worldwide, the pharmaceutical industry is one of the most strategically important and priority areas of government regulation of state problems.

According to acts adopted within the European Union, both manufacturers located in the Union or non-EU countries and wholesale distributors distributing pharmaceuticals for medical use in the EU are subject to regular inspections. The authorized bodies of the member countries have an assessment system that provides for inspections of the premises of manufacturers, importers or distributors of pharmaceutical substances located on their territory with the necessary frequency and their effective follow-up. Moreover, the frequency of inspections is determined not only by general requirements (at least 1 time in 3 years), but also by the characteristics of the production itself - the higher the risk of non-compliance (for any reason, both objective and subjective) with the rules and guidelines of relevant practices, the higher the frequency inspections.

If there are grounds for non-compliance with legal requirements, including the principles and guidelines of good manufacturing practice and good distribution practices, the authorized body has the right to inspect the premises of manufacturers and distributors of pharmaceutical substances located in non-EU countries, as well as manufacturers or importers of excipients.

In addition to inspections at the request of the authorized body of a particular member country, pharmaceutical inspections can also be carried out in the Union and countries outside it, at the request of any country - member of the EU, EC or the European Medicines Agency (hereinafter – "**the EMA**"). In addition, inspections may be carried out at the premises of the holders of registration certificates. At the special request of the manufacturer, the authorized body of the interested member country is entitled to conduct inspections of manufacturers of raw materials.

Moreover, representatives of the authorized body conducting pharmaceutical inspections (inspectors) are vested with the following rights:

• inspect the production and commercial enterprises of pharmaceuticals manufacturers, pharmaceutical substances and excipients, as well as any laboratories engaged by the production license holder, in order to conduct pharmaceutical inspections;

• take samples, including for the purpose of conducting independent tests by an official laboratory for the quality of medicines control or a laboratory selected by a member country for these purposes;

• evaluate any documents related to the subject of pharmaceutical inspection in accordance with GxP.

The methodological basis for inspections (including terms and definitions, description of procedures, training, types of inspections, certificate forms, notifications, permits and notifications, etc.) is the Community Inspection and Exchange of Procedures compilation, compiled jointly by the EC and EMA and regularly updated (currently contains 221 pages). Based on the results of the pharmaceutical inspection, a decision is made to issue a certificate or the need to bring production conditions in line with the principles and rules of good manufacturing practice. In the latter case, depending on the categories of discrepancies, a shutdown of the production process and/or withdrawal of the medicine (other material) from circulation may follow.

The price processes taking place in the pharmaceutical market are extremely complex and diverse. On the one hand, pricing is an integral part of the economic policy of the state, on the other hand, when determining the cost of medicines, it is necessary to consider a number of social, legal and moral aspects. In addition to production and market factors, regulatory and financial-legislative mechanisms have a significant impact on medicine pricing.

According to official reports of the World Health Organization (hereinafter – "**WHO**"), medicine provision in the EEC countries is not only well organized, but also tightly controlled and regulated. Among other instruments for regulating the pharmaceutical market (licensing, registration of medicine), one of the leading places is price regulation. In Europe, states control the wholesale and retail sales of medicines, their proper distribution and use, determine the rate of return.

In almost all European countries, prices for medicines are regulated in various forms, depending on the tools and methods of influencing participants in the pharmaceutical industry. It is especially important to emphasize that both medicine prices paid from state funds and sold according to a doctor's prescription and prices for non-prescription medicines, i.e. sold freely without requiring a doctor's prescription.

European countries use combinations of these solutions, although the goal of governments remains the same: control of medicines spending and the creation of an effective mechanism to contain health care costs within the framework of the adopted budget.

For example, in Germany, reference price calculations are carried out in several stages. First, for each interchangeable medicine, the costs associated with the daily intake for all its finished forms, package sizes and dosages are calculated.

Next, the average daily dose price median is determined for all medicines with the same active substance, and then for all interchangeable group medicines. As a result, the reference price for the group is the price of the medicine, the average daily dose of which is equal to or close to the median value. In Sweden, the reference price is determined by adding 10% to the price of the cheapest generic medicine. In Denmark, the reference price is calculated as the arithmetic average of the prices of the two cheapest medicines of this pharmacotherapeutic group. In Canada, a reference pricing system applies to medicines under patent protection. Their prices are set in accordance with the principle of international reference prices, compared with a basket of prices for similar medicines in six European countries (Great Britain, Germany, France, Italy, Switzerland, Sweden) and the USA. The price of an innovative medicine brought to the Canadian market cannot be higher than the median price in the international basket, and the price of all categories of patented medicines cannot exceed the highest prices for the same medicines in the 7 indicated countries.

Increasing the prices for already patented medicines on the market are possible only within the inflation rate.

In Canada, medicine price control at the federal level is carried out by an independent body, the Federal Chamber for the Review of the Price of Patented Medicines. The chamber does not set prices. Its task is to prevent prices set by the manufacturer on proprietary medicines from being overstated.

The Chamber mainly controls the prices of proprietary medicines, to a lesser extent generic one. Various approaches can be applied in pricing: using forms, refusing generics, setting prices for medicine reviews, freezing prices, controlling margins in factories, pharmacies, and risk planning. The chamber reports to the Minister of Health and Parliament.

In general, overstatement is determined by the following criterion: the price of a medicine can be limited so that the costs of treatment are not higher than those for similar medicines of a particular pharmacotherapeutic group.

It is well known that the quality of pharmaceutical products is laid down at the production stage and the safety of pharmaceutical products is of paramount importance for the health protection. In this regard, medicine authentication technologies can make an important contribution to maintaining the integrity of the pharmaceutical supply chain. World trends are such that today in a number of countries projects are being intensively developed, the purpose of which is to build a system of verification and traceability of medicines.

In 2011, the European Union (hereinafter – "**the EU**") began to develop regulatory measures aimed at ensuring the safety of medicines and the security of the supply chain of pharmaceutical products. In this regard, Directive 2011/62/EC of the European Parliament and the Council of Europe was developed, aimed at tightening control measures in the supply chain of medicines and preventing the counterfeit medicines sale. At the same time, the EU does not establish requirements regarding using serialization methods, each country has the right to introduce its own model (2D barcode, RFID, etc.).

In particular, Directive No. 2011/62/EU provides:

• a unique identifier should be marked by the manufacturer on prescription medicines;
• maintaining a "list" of prescription medicines that do not need codification due to their low cost, limited release, physical impossibility of counterfeiting, etc.;
• maintaining a "list" of OTC medicines requiring codification because of their high price, high demand, brand recognition and the presence of counterfeit medicines in the medicine supply chain;
• both lists are planned to be used at EU level. However, manufacturers will not be able to make decisions on the codification of medicines.

Overall, the Directive reflects a potential long-term strategy for enhancing the safety of the medicine supply chain. In particular, technology support is defined as a key element in solving the problem of counterfeiting. This reflects a growing mutual understanding of the international community, which increases the potential for product identification and control to protect consumer health and safety, and about the important role that technology can play in the fight against counterfeiting.

Turkey is one of the countries in which the traceability system covers all prescription medicines. ITS (İlaç takip sistemi) - the Turkish medicine tracking and tracking system (hereinafter referred to as the System), is the first successfully implemented medicine tracking system in the world. Five years were allocated for the implementation of the system. The system allows you to track each package of the medicine to ensure a reliable legal supply chain from the manufacturer to the patient.

To implement the system, the following main works were performed:
- development of regulatory legal acts and methodology governing the operation of the system;
- introduction of mechanisms for applying unique markings to each package of medicines in the form of a two-dimensional code in the Data-matrix format;
- development and implementation of a centralized database "ITS" for the collection, processing and storage of data at unique marks;
- development and implementation of PTS web services to automate the process of data transfer between participants in the supply chain at unique marks (during transportation of medicines);
- development and implementation of a mobile application for the population, allowing to obtain information about each unit of medicines (to perform the function of "public control").

To ensure uniqueness, a two-dimensional code in the Data-matrix format is applied to each package of the medicine. This technology is the most economical, reliable and most suitable of all possible marking methods (linear bar code, QR, RFID, etc.).

The owner of the System is the Ministry of Health of Turkey. Moreover, until 2010, the Agency was the developer of the System.

In order to facilitate the integration process of all interested parties, the implementation of the System was divided into two phases. During the first phase (from 2010 to 2011), the accounting of 2 mandatory notifications (processes) was automated:

• registration of goods in the system by the manufacturer/importer;
• delivery of goods by pharmacies/hospitals under state insurance.

Operations such as purchase, return, sale, consumption, destruction, etc., were not required. Information from pharmacies and hospitals about dispensed medicines was transmitted to the regulator of the state insurance system for subsequent cost recovery. In the absence of information on medicine dispensing in the System, the state did not make insurance payments. Thus, only distribution companies, pharmacies and medical institutions that were ready for integration could participate in the insurance system.

In 2012, the second phase of the implementation of the system was launched, covering all participants in the pharmaceutical market: manufacturers, distributors of warehouses, hospitals, and pharmacies.
The state obliged all distribution companies to register procurement and sales transactions in the system. Accordingly, the system automatically records all operations for all participants in the pharmaceutical market.

Since, according to the results of the first phase of implementation, manufacturers and pharmacies / hospitals worked in the System, the main problems of the second phase of implementation were associated with distribution companies. The following implementation problems were noted:

- on the Turkish pharmaceutical market were 2 main distribution companies that impeded the implementation of the system: Selçuk Ecza Deposu ç.ş. (43%), Hedef Alliance (27%);

- the qualifications of most small distribution companies were low.

The full system implementation cycle was completed in 2012. Since 2014, at the end of the main stages of implementation, a mobile application was launched for the population in order to verify the authenticity of medicines. Using a mobile application based on scanning data from packaging barcodes, anyone can make sure that the specified data matches the medicine label (manufacturer, expiration date, actual price, pharmacy / hospital balance, etc.). The application is available on all major platforms: AppStore, Google Play, Windows Phone and Windows Store.

After the implementation was completed, the system support was outsourced to the TIGA information Technologies IT company. Maintenance includes not only ongoing work on the System, but also its constant improvement based on the results of the analysis and instructions of state structures. For example, the forthcoming coverage of medical products and cosmetics, the transformation of the System with the possibility of making decisions on it, the introduction of a risk management tool, and more.

On February 1, 2017, an experiment began in Russia on the labeling of medicines with special control signs, which lasted until December 31, 2017. The experiment is coordinated by the Ministry of Health, and the operator of the created labeling system is the Federal Tax Service of Russia.

The purpose of the labelling introduction is to counter the production and circulation of counterfeit and fake products. As a result of the experiment, an information system for monitoring the turnover of medicines will be developed. The buyer will be able to check the medicine immediately upon purchase at the pharmacy - just scan a two-dimensional barcode with a special scanner or smartphone.

At the initial stage, it is planned to label more than 60 types of medicines, including 10 trade names of medicines intended for the treatment of high-cost nosologies, and more than 30 trade names of medicines from the list of vital and most important medicines.

The willingness to participate in the pilot project was expressed by 23 medicine manufacturers, four major pharmaceutical distributors, more than 30 medical organizations and more than 250 medicine retail companies, including pharmacy chains of federal and regional scale.

If 100% of manufactured medicines are marked, the monitoring system will track about 6 billion packages of medicines per year and will cover more than 350 thousand participants in the turnover, including about 1000 domestic and foreign manufacturers of medicines, over 100 thousand medical and 250 thousand pharmacy organizations.

In this way, the innovations and additions proposed in the draft Code regarding pharmaceutical inspections, the introduction of a traceability system for medical products and the introduction of a system of state regulation of medicine prices will contribute to the harmonization of national legislation with international norms and requirements and will allow for the achievement of efficiency, coherence and transparency of actions as on the part of regulatory authorities, and by the pharmaceutical market.

There is wide international and domestic experience in the functioning of the electronic procurement platform. This is a purchase at the level of international organizations, as well as individual countries (European, USA, Canada).

The procurement of WHO requalified medicines is widely used by European countries and is a tool for purchasing quality medical products in a short time. Every year, international procurement organizations such as UNICEF, the Global Fund to Fight AIDS, tuberculosis and malaria and UNAIDS, or through them, procure medicines worth billions of US dollars for their subsequent distribution in countries.

Along with this, there are recommendations of NICE, EMA, BNF on the need to observe the principle of patient orientation when purchasing medicines for individual patients in case of intolerance or vital indications, when long-term replacement of medicine therapy is not recommended for the effectiveness of treatment. So, following the recommendations of NICE, prescribing should be limited by the prevalence of benefits over risk.

The creation of a logistics network is due to the need to guarantee the preservation of the quality of medicine throughout the supply chain from producer to consumer, harmonization with European requirements, the requirements of OECD countries. In international practice, such national distributors as NHS National Services Scotland (Scotland), Pharmaniaga Logistics (Malaysia) have their own logistics network.

To improve the rights and obligations of medical and pharmaceutical workers

In Ukraine, the Doctor's Code stipulates that the main goal of a doctor's professional activity (practitioner and scientist) is to preserve and protect human life and health in the perinatal and postnatal period, prevent diseases and restore health, as well as reduce suffering in incurable diseases, at birth and onset of death. The ethical attitude to the patient's personality does not stop even after his death. The doctor's actions when applying the latest medical technologies (transplantation of human organs and tissues, interventions in the human genome, reproductive function and the like) are determined by the ethical and legislative acts of Ukraine, recommendations and requirements of the World Health Organization, UNESCO Bioethics Committee and the Commission on bioethics preservation and protection of human life and health in the perinatal and postnatal period, disease prevention and restoration of health, as well as suffering reduction with incurable diseases, birth and death. The ethical attitude to the patient's personality does not stop even after his death.

To protect the rights of a doctor in Russia, a law has been developed on the protection of medical workers from violent attacks in the performance of their duties.

To solve the problems of rural provision with doctors, the Zemskyi Doctor state program was adopted and is in force from 2018 to 2020, which provides preferential conditions for highly qualified rural specialists.

In the United States, a physician's responsibility for harming a patient's health is established by state general law. The country does not have a national (federal) law on the professional responsibility of a doctor or a law relating to issues of inappropriate medical practice (or negligence of a doctor). State courts

establish common law principles based on decisions made in individual cases (case law). A similar principle originally came from English common law (which operated on the territory of the American colonies until the formation of the United States as a sovereign state); in this way, these principles practically do not differ from those existing in the territory of other former British colonies - Canada and Australia. Since then, the courts of individual countries continued to develop legislation on their own, so the laws of each country, and in the US - of each state - have their own characteristics. Despite this, the general principles on the basis of which a decision is made on the doctor's responsibility for harming the patient are common to all states and practically do not differ from those operating in Western countries, including states with common and civil law systems.

In order to receive damages from a doctor, an injured patient must prove the following four signs of the doctor's negligence (and four elements of the statement of claim):

1) doctor had an official duty to be careful about a patient;
2) doctor did not fulfill this obligation, acting in violation of the professional standard with respect to the diagnosis and treatment of the patient established for this case (thus showing professional negligence);
3) patient's health was really harmed;
4) harm caused to the patient's health is a direct consequence of the doctor's failure to fulfill his duties (negligence).

Joint Commission for the Quality of Medical Services

International experience shows that the results of the transfer of functions by the state are successful in mutual cooperation.

For example, in Germany there is a Federal United Committee (hereinafter – "**the FUC**"), which, within its competence, issues directives for all sectors of the health care system in the compulsory social health insurance system. Directives adopted by the FUC are mandatory for entities operating in the social health insurance system.

Funding for the FUC is provided by the Federal Parliament.

Directives are adopted at the plenary meeting (plenum) of the FUC, which is the supreme governing body. The plenum includes representatives of the founders: the German Medical Chamber and the Association of German Hospitals (5), representatives of the Social Health Insurance Fund Association (5), independent members (3) and representatives of the Patients Association (5).

The FUC is the main regulator, which represents the interests of professional persons (medical workers) and business entities (hospitals) that make decisions.

The German Medical Chamber of Germany, to which the state has transferred control over the full range of professional activities, including certification, certification of specialists, as well as the implementation of the postgraduate continuing education system. All doctors require compulsory membership.

In the United Kingdom since 1858, in accordance with the law, the General Medical Council (hereinafter – "**the GMC**") has been operating in the United Kingdom, in which about 200 thousand practitioners are united. The principle of regulation is based on the principle of quasi-regulation. For such organizations, a characteristic feature is the regulation of the relevant industry or market segment.

The main objectives of the GMC are:

- establishing standards of professional activity;
- monitoring of compliance with standards by members of the organization, the application of sanctions for violation of standards;
- work with consumer complaints and dispute resolution;
- maintaining a register of members.

Similar organizations were also created for various branches of medicine: pharmaceuticals, auxiliary medical personnel, and individual medical professions.

According to UK law, physicians who are not part of these organizations may also have healthcare practices. However, due to British traditions and historical past, the demand for these specialists is much lower, which also manifests itself in their level of remuneration. According to statistics, only about 10% of doctors carry out their activities, not being a member of the relevant professional organization in the UK.

Another example is the Japan Medical Association. Founded in 1916 and then recreated in its current form in 1947, the mission of the association is to ensure the management of doctors and promote high standards of medical care for all Japanese citizens. Membership in the Japanese Medical Association is 165,000, or approximately 60% of all licensed doctors in Japan.

The Japanese Medical Association operates through contributions from members who are financially independent of the state government. The separation of powers allows the Ministry of Health, Labour and Social Welfare of Japan to formulate health policy, and the medical association to protect the health of citizens by providing medical care to patients and continuously improve the education level of Japanese physicians.

In 1987, the Madrid Declaration on Professional Autonomy was published by the World Medical Association. In the same year, the Japanese Medical Association began to introduce continuing education programs for medical education to ensure the effective participation of doctors within the framework of a philosophy of professional autonomy based on self-regulation.

In this system, doctors voluntarily and independently seek to improve clinical capabilities and study the main health problems. One of the organization's goals is to ensure a trusting relationship between doctors and patients, while maintaining the high quality of medical care.

One of the objectives of the association is to collect information from members of the association, which, in their professional opinion, should be enriched or improved by the health system. And subsequently, this information is transmitted to the government to implement reforms in the medical services field. Moreover, it is important to provide the necessary and sufficient funding to achieve these reform plans through the government.

The activities of the Japanese Medical Association are aimed at fulfilling the basic principles of ethics. The task of health organizations is the treatment of diseases, maintaining and strengthening people's health; and based on the realization of the importance of this mission, the doctor must serve the community.

The Japanese Medical Association aims to make every effort to further improve the health system, not only in Japan, but also to contribute to international activities through the World Medical Association and CMAAO.

In the United States, professional medical associations play a key role in regulating the healthcare industry. Their number is quite large: there are national, regional, city associations, associations in certain specialties, and others. The largest in the state is the American Medical Association, functioning since 1847, whose main functions are to ensure a high level of professionalism in medicine; protection of the rights and interests of doctors and patients, the formation of policies in the medical education field, ethical policies and others.

Similar organizations exist in France, Italy, Austria, Great Britain and others. Their significance is quite large, since they provide the professional medical community with participation in the management of the healthcare industry, in the public and political life of the state. At the same time, the national ministries are assigned the general management functions of health care, construction of medical institutions and their material and technical support, and control over the fulfillment by law of medical associations of legislatively assigned duties.

An analysis of the foreign countries experience shows that the institutional basis for the transfer of state functions and public administration in health care arose long ago. During this time, many developed countries have put into practice the methods of public administration along with state.

As a result, acting through their professional associations, foreign doctors are convinced that the new system for organizing the medical services provision is superior to alternative management methods.

10. Estimated financial costs associated with the implementation of the draft law

Given the global challenges associated not only with demographic and epidemiological forecasts, but also with the increase in costs associated with the medicine digitalization and the constant introduction of new medical technologies for the diagnosis and diseases treatment, the goal of compulsory health insurance is to ensure sustainable development, an equitable distribution of the burden of financing and comprehensive risk protection health systems.

Despite the annual increase in budget funds allocated for financing the guaranteed volume of free medical care, over the past 5 years there has been an increase in pocket expenses of the population for health services, which in 2017 amounted to 678 billion tenge. The share of pocket spending reached 41% of total health care spending, which is twice the level recommended by the World Health Organization (20%). At the same time, more than 30% of private expenses goes to the purchase of paid medical services declared under the guaranteed volume of free medical care.

This is primarily due to the certain underfinancing of the guaranteed volume of free medical care, which today is estimated at more than 362.5 billion tenge, including 164.3 billion tenge for outpatient care and 126.1 billion tenge for inpatient care, for rehabilitation services 18.3 billion tenge, etc.

For today the calculations of health care expenses have been made up to 2030 and consist of:

Health care expenses in 2018 amounted to 940.9 billion tenge. In 2030, health care expenses will amount to 2943.7 billion tenge, including accumulated funds, including at the guaranteed volume of free medical care - 1,546.7 billion tenge, in the compulsory health insurance system - 1,397.1 billion tenge.