

РОЗДІЛ 1

ТЕОРІЯ ТА ІСТОРІЯ ДЕРЖАВИ І ПРАВА; ІСТОРІЯ ПОЛІТИЧНИХ І ПРАВОВИХ УЧЕНЬ

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TRENDS IN THE DEVELOPMENT OF MEDICAL LEGISLATION OF UKRAINE: HEALTHCARE ASPECT

ТЕНДЕНЦІЇ РОЗВИТКУ МЕДИЧНОГО ЗАКОНОДАВСТВА УКРАЇНИ: ОХОРОНОЗДОРОВЧИЙ АСПЕКТ

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In the article the review of the assessing of the impact of health regulations on the effectiveness of public health policies in Ukraine is done.

The scientific novelty of article is consists in a comprehensive analysis of the current state of medical legislation of Ukraine in the conditions of modern challenges and threats to the functioning of the health care system and the protection of the rights of patients.

There are considered the issues, that need legal regulation in the field of health care in Ukraine: the ensuring the rights of patients to quality medical devices; the regulation of the procedure for the use of medical cannabis for medical purposes; the providing medical care to patients, who refuse hospitalization; the introduction of the institute of previously expressed wishes for medical interventions; the updating legislation in the field of abortion.

It's analysed the prospects of the preparation of the Medical Code in Ukraine, which will facilitate the professional activities of medical and pharmaceutical workers, ensure the implementation of the state-guaranteed right of all citizens to receive medical care and improve their health.

Effective implementation of the health care system reform is impossible without taking into account all its components, in particular: social guarantees, legal liability (administrative, criminal) for offenses in this area and ensuring the optimal model of proceedings against them. The introduction of measures of social protection and legal responsibility in this context will help strengthen the capacity of the health care system of Ukraine to counter the spread of the coronavirus pandemic. The development of e-government, the introduction of «E-medicine» in the field of intersectoral social relations are designed to simplify not only the social and managerial aspects of health care, but also the implementation of proceedings on administrative offenses, criminal proceedings due to social and legal conflicts in the field of security health and the commission of relevant offenses.

Key words: medical legislation, patients, Medical Code, health law.

У статті здійснено огляд оцінки впливу норм медичного законодавства на ефективність державної політики у сфері охорони здоров'я в Україні.

Наукова новизна статті полягає у комплексному аналізі сучасного стану медичного законодавства України в умовах сучасних викликів і загроз функціонування системи охорони здоров'я та захисту прав пацієнтів.

Розглянуто питання, що потребують правового регулювання у сфері охорони здоров'я в Україні: забезпечення прав пацієнтів на якісні вироби медичного призначення; регулювання порядку використання медичної коноплі в медичних цілях; надання медичної допомоги хворим, які відмовляються від госпіталізації; запровадження інституту попередньо висловлених побажань щодо медичних втручань; оновлення законодавства у сфері абортів.

Проаналізовано перспективи підготовки в Україні Медичного кодексу, який сприятиме професійній діяльності медичних і фармацевтичних працівників, забезпечить реалізацію гарантованого державою права всіх громадян на отримання медичної допомоги та зміцнення свого здоров'я.

Ефективна реалізація реформи системи охорони здоров'я неможлива без урахування всіх її складових, зокрема: соціальних гарантій, юридичної відповідальності (адміністративної, кримінальної) за правопорушення у цій сфері та забезпечення оптимальної моделі провадження щодо них. Запровадження заходів соціального захисту та правової відповідальності у цьому контексті сприятиме посиленню спроможності системи охорони здоров'я України протидіяти поширенню пандемії коронавірусу. Розвиток електронного урядування, впровадження «E-medicine» у сферу міжгалузевих суспільних відносин покликані спростити не лише соціальні та управлінські аспекти охорони здоров'я, а й здійснення провадження у справах про адміністративні правопорушення, кримінального провадження за вчинення відповідних правопорушень.

Ключові слова: медичне законодавство, пацієнти, Медичний кодекс, право про охорону здоров'я.

Introduction. The field of health care is an extremely important and priority direction on the way to building a constitutional and socially oriented state. Article 49 of the Constitution of Ukraine proclaims the right of everyone to health care, medical assistance and medical insurance. Changes in the health care system caused by the SARS-CoV-2 pandemic need to update the model of legal regulation of the medical sphere in the world in general and in Ukraine in particular. An important component in this context is to achieve positive results by guaranteeing all citizens equal access to medical services at minimal resource costs.

The basis of decisive steps in building a modern national health care system is the adequacy of funding for the medical sector, the effectiveness of legal regulation of medical care and medical services [1, p. 12], the existence of effective means of legal liability for government officials, medical and pharmaceutical workers for decision-making, taking action or preventing inaction in the field of health care and forming new approaches in the implementation of state policy in the field of medical education.

A feature of health care legislation is the large number of legal acts of various legal forces that are part of it. This complicates the application of health regulations, which highlights the idea of preparing a Medical Code, which should combine the key issue of legal regulation – the balance of rights and responsibilities of patients and health professionals. The process of reforming medical legislation depends on the role of human-centred values in the activities of public authorities. Despite the declaration of the rule of law at the stage of creating new regulations, it is allowed to ignore its basic principles.

Human health is also regarded as an object of national security of the state, which requires not only social and legal protection, but also administrative and criminal protection, which provides for the application of proper legal procedure in administrative and criminal proceedings for offenses against population health.

Thus, the term «health care» is multifaceted, has a comprehensive cross-sectoral nature and requires a multidisciplinary approach.

The purpose of the article is to review the assessing the impact of health regulations on the effectiveness of public health policies in Ukraine.

Main part. Modern conditions of development require systemic and comprehensive changes in the field of health care.

The development of health legislation depends on the general state policy in the field of health care, with the regulation of public relations by the state, the establishment of rules of conduct of executive authorities, local government in the field of health care [2]. We agree, that the medical reform, that has been implemented in Ukraine since 2016, demonstrates the active promotion of approaches that were not previously inherent domestic medicine, in terms of financing medical care and elements of the organization of health care [3, p. 127].

With the establishment of centralized and local levels of health care, the issue of providing an adequate level of medical care to patients and guaranteeing health rights to the lower-income citizens is the main criterion of the health care system. Not the least role in this process is played by medical legislation. A centralized level of health care management only nullifies efforts to effectively and efficiently reform the health care sector. Decentralization of health services can lead to the spread of unregulated commercialization of health care, reduced access to health care, deteriorating health care, unbalanced and uneven development of health care at the regional level.

With regard to the legal regulation of relations arising in the field of health care, it is necessary to refer to the world experience of building relationships between patients, doctors, medical institutions and the state, taking into account

the financial, legal and socio-legal aspects. In European countries, models of the health care system can be divided into two types: budget (public) and insurance (social insurance).

A characteristic feature of the budget model (Great Britain, Portugal, Ireland, Italy, Greece and Spain) is the significant role of the state and the financing of the system through tax revenues. Medical services for the whole population are provided free of charge. Private insurance plays an additional role in the health care system. Medical service providers receive budget funds under the control of private management companies.

The insurance model (Poland, Germany, France, Austria and Belgium) is defined as a system of managed social health insurance, combining the market of medical services with a developed system of state regulation and social guarantees. Most services (package of medical guarantees) are provided according to the approved list in accordance with the legislation on medical social insurance by medical institutions of various forms of ownership, mainly private non-profit institutions. Primary care is provided by family practitioners. Private health insurance plays an additional role.

There is a third model in the world – private (private or market) (USA, Israel, South Korea), which is characterized by the provision of medical services on a paid basis, through private insurance and citizens' own savings. There is no single system of state health insurance. The market plays a key role in meeting the needs of health services.

An important component of reforming Ukraine's medical legislation is the discussion on the introduction of compulsory health insurance, taking into account the experience of European countries.

On 27 August 2004, the Republic of Poland adopted the Law on Public Financing of Health Care [4], which clearly defined the procedure for financing the Polish health care system through personal contributions to the Fund, which in cooperation with state bodies provides medical services.

Compulsory health insurance was introduced in Lithuania in July 1997 in accordance with the Law of the Republic of Lithuania on Health Insurance [5]. According to the act, there are two types of insurance: compulsory and additional (voluntary).

Estonia is one of the countries that is actively implementing innovations in the field of medicine, which has increased the efficiency of the health care system and the quality of medical services. During the reforms in the 1990s, the principle of separation of buyers and suppliers was introduced, which increased the quality of primary health care by providing free choice of provider of such services. In 1991, the Law on Health Insurance was adopted [6], which provided funding for almost all health services, including immunization through the social health insurance system. The latter is financed mainly by the targeted payroll tax.

A feature of Ukrainian medical legislation is the existence of an incorporated act – the Fundamentals of Health Care Legislation of 1992 [7], which defines the legal, organizational, economic and social principles of health care in Ukraine. During the thirty years of Ukraine's independence, the realities of the socio-economic system need to update the Fundamentals of Health Care Legislation. The legal settlement of the problems of providing the medical care system with financial resources, guaranteeing medical services to the lower-income citizens, rational and transparent distribution and use within this system and consolidating the social nature of funding for health care institutions needs urgent improvement.

Improving health legislation raises the issue of codification. It is not a question of mechanical unification of the current laws, but of change of the maintenance of the legal norms connected with a subject of legal regulation – the right to public health services, their unification in the uniform regulatory legal act. The development and adoption of the Medical Code will facilitate the professional activities of medical and pharmaceutical

workers, as well as ensure the implementation by the state of the necessary amount of medical services to citizens and improve their health.

Health law as a component of medical legislation is evolving under the influence of the practice and evolutionary standards of the European Court of Human Rights. Statements on the quality and adequacy of health care are subject to examination in the context of Articles 2 «Right to Life» and 8 «Right to respect for private and family life» of the Convention for the Protection of Human Rights and Fundamental Freedoms (hereinafter – the Convention).

The positive responsibilities of the State under Article 2 of the Convention are limited to the establishment of national redress mechanisms, the implementation of which will allow to assess the quality and adequacy of the treatment received at the national level. The imperfection of the rules established by the State can in essence be regarded as the State's lack of desire to protect persons under its jurisdiction, which leads the Court to find a violation of Article 2 of the Convention [8]. The shortcomings of national legislation create a situation where, even in the case of criminal proceedings, the pre-trial investigation body cannot establish the responsible person of the health worker. In view of this, there are no de facto guarantees for patients to preserve medical information and the right to privacy at the national level.

An important part of the medical legislation of Ukraine today is the regulations adopted to prevent the spread of coronavirus SARS-CoV-2.

The system of the legislation' regulations preventing the spread of coronavirus SARS-CoV-2 consists of the following acts [9]: 1) laws of Ukraine; 2) decrees and orders of the President of Ukraine; 3) resolutions and orders of the Cabinet of Ministers of Ukraine; 4) acts of the Ministry of Health of Ukraine; 5) decisions of the State Commission on Technogenic and Ecological Safety and Emergencies; 6) resolutions and orders of the Chief Sanitary Physician of Ukraine; 7) municipal and local legal acts.

The legislation of Ukraine on administrative liability provides for liability for violation of rules on quarantine of people, sanitary and hygienic, sanitary and anti-epidemic rules and regulations provided by the Law of Ukraine «On Protection of Infectious Diseases», violation of rules for staying in public buildings, structures, public transport during the time of quarantine without wearing personal protective equipment [10; 11].

Criminal liability is also provided for violation of sanitary rules and norms on prevention of infectious diseases (Article 325 of the Criminal Code of Ukraine). As the COVID-certificate is a document, criminal liability is provided for its forgery and use (Article 358 of the Criminal Code of Ukraine). If a forged COVID-certificate is made by unauthorized alteration of information contained in automated systems, in particular, the electronic health care system, by a person who has access to it, such person will be liable under Article 362 of the Criminal Code of Ukraine and may receive a fine of two thousand to four thousand non-taxable minimum incomes (from UAH 34,000 to UAH 68,000) or correctional work for up to two years [12].

Health care is also guaranteed during criminal proceedings [13]. For example: (1) in the context of openness of the proceedings, the investigating judge or the court may decide to restrict access of persons who are not participants in the trial to the court session during quarantine established by the Cabinet of Ministers of Ukraine under the Law of Ukraine «About protection of population from infectious diseases», if participation in a court hearing will endanger the life or health of a person (Part 2 of Article 27 of the Criminal Procedure Code of Ukraine); (2) if long-term storage of material evidence is dangerous to human life or health, they are transferred for technological processing or destroyed by the decision of the investigating

judge, court (Part 6 of Article 100 of the Criminal Procedure Code of Ukraine); (3) the application of measures of physical influence that may harm the health of a person is prohibited (Part 3 of Article 143 of the Criminal Procedure Code of Ukraine); (4) the state of health of the person is taken into account when choosing a preventive measure (Article 178 of the Criminal Procedure Code of Ukraine); (5) the use of electronic means of control that may pose a danger to the health of the person using them is not allowed (Part 4 of Article 195 of the Criminal Procedure Code of Ukraine); (6) the official responsible for the detention of detainees is obliged to ensure the immediate provision of appropriate medical care and fixation by the medical worker of any bodily injuries or deterioration of the detainee's health (Part 3 of Article 212 of the Criminal Procedure Code of Ukraine); (7) investigative (search) actions are not allowed if there is a danger to human health; etc. In addition, the Criminal Procedure Law of Ukraine provides criminal proceedings for the application of coercive measures of a medical nature (Chapter 39 of the Criminal Procedure Code of Ukraine), which has features and is regarded as a differentiated procedural form.

Despite significant steps by the state, the current development of medical legislation in Ukraine in the context of guaranteeing the right to health lags behind global and Western European trends in legal regulation. We suggest you pay attention to such as:

1. Ensuring patients' rights to quality medical devices.

The Ministry of Health of Ukraine has developed a draft Law on Medical Devices, which should regulate the following issues: creation of levers of influence on the circulation of counterfeit medical devices; assistance in regulating the advertising of medical devices; regulation of clinical trials of medical devices. In addition, it is envisaged that manufacturers and importers of medical devices will be able to undergo a conformity assessment procedure through remote audits, as well as provide instructions for the use of medical devices in electronic form.

This is important in the context of strengthening legislative, regulatory and instructional documents governing the legal circulation of medicaments [14].

2. Regulation of the use of medical cannabis for medical purposes. Medical legislation may establish conditions and an exhaustive list of cases of medical cannabis use. The implementation of the relevant rules depends on the quality of clinical trials and observational data [15, p. 1–2].

The Parliament of Ukraine has registered a draft law on regulating the circulation of cannabis for medical purposes, scientific and technical activities (№ 5596) [16], which proposes to exclude medical cannabis from the register of narcotic substances and the circulation of medicinal cannabis, products of its processing and medicines made from medicinal cannabis should be allowed in scientific and scientific-technical activities, as well as in medical practice – provided that control is ensured at all stages. Dispensing of medicines made from medicinal cannabis was offered only on prescription. Note that in December 2020, the UN Commission on Narcotic Drugs decided to remove medical cannabis from the list of the most dangerous drugs.

3. Settlement of the issue of providing medical care to patients who refuse hospitalization. Adult patients who are able to decide on medical care may agree to or refuse treatment. Patients who are unable to make their own decisions may be provided with emergency care, including ongoing hospitalization. This issue is especially relevant in cases of mental health problems. The issue of rehabilitation of patients who are discharged from a medical institution, but who can't make their own decisions [17] is subject to settlement.

4. Implementation of the institute of previously expressed wishes for medical interventions. Acts of medical law of Ukraine do not enshrine the patient's right to prior

medical order and the obligation of medical professionals to take it into account in the decision-making process when providing medical care, nor does it determine the appropriate implementation procedure. Only the Law of Ukraine «On the Application of Human Anatomical Materials» provides the right of a person to give written consent or non-compliance with the removal of anatomical materials from his body for transplantation after death, to withdraw such a statement, to give new written consent or disagreement to posthumous donation, appointment of an authorized representative, who after the death of this person will agree to remove from his body anatomical materials for transplantation and / or manufacture of bio implants [18; 19].

Legislative consolidation of the institute of pre-expressed wishes is definitely necessary to properly and fully ensure the patient's right to participate in decision-making in the process of providing medical care and will promote the implementation of European standards in the field of biology and medicine. Achieving this goal is possible by establishing an effective legal model not only of prior medical order, but also its change and revocation, taking into account possible changes in the patient's position and new advances in medicine, the possibility of appointing an authorized person who will allow the patient freedom, maintaining a reasonable balance between the previous order and ensuring the best interests of the patient. However, it is necessary to take into account possible problems in application of the law to such cases, which are noted by researchers from countries where such institutions have already been implemented [20, p. 61–62].

Separately, the publications draw attention to the exercise of the right to consent of minor patients when granting permission for medical intervention. There are the following options for exercising the right to consent of a minor patient and the right of parents (guardians, family members) to grant permission for medical intervention:

1) if the consent to medical intervention is given by both subjects of medical legal relations, then there are no problems for medical practice;

2) if the patient – a minor gives personal consent to medical intervention, and, for example, parents do not give consent. The problem arises for the medical worker who has to carry out a medical intervention, but has no legal grounds to do so, as is not able to obtain consent for the necessary intervention in full [21].

5. Update legislation in the field of abortion. Recently, the issue of abortion in the context of state demographic

policy has become relevant [22, p. 711]. As an example, on October 22, 2020 in the Republic of Poland, the decision of the Constitutional Court determined that abortion due to fetal pathology is unconstitutional. Exceptions to this constitutional prohibition are pregnancies that endanger a woman's life or that a woman becomes pregnant as a result of rape or incest.

Conclusions. The current realities of social development due to the SARS-CoV-2 pandemic are characterized by a set of interrelated factors in which the importance of the legal regulator of public relations may play a secondary role. The novelties of the Ukrainian legislation in the field of health care are aimed at the emergence of fair competition in the field of medical services, as well as the maximum preservation of social guarantees in the field of health care for the lower-income citizens.

At the same time, the scientific and technological empowerment of the globalizing world has a negative impact on the inviolability of individual human rights and freedoms – new medical knowledge and technology can be used not only for the benefit of individuals. There is a need for a scientific search for optimal legal means of regulating the field of health care. This level of regulation of health care can be explained by the need to support low-income citizens who need an adequate level of health care. The state-guaranteed right of everyone to health care belongs to the priority areas of state regulation and influence, is part of the national social protection system, and therefore should be provided by coercive measures (administrative and criminal).

Effective implementation of the health care system reform is impossible without taking into account all its components, in particular: social guarantees, legal liability (administrative, criminal) for offenses in this area and ensuring the optimal model of proceedings against them. Practice shows the timely response of the Ukrainian state to the challenges of the spread of the SARS-CoV-2 pandemic by amending the legislation. The introduction of measures of social protection and legal responsibility in this context will help strengthen the capacity of the health care system of Ukraine to counter the spread of the coronavirus pandemic. The development of e-government, the introduction of «E-medicine» in the field of intersectoral social relations are designed to simplify not only the social and managerial aspects of health care, but also the implementation of proceedings on administrative offenses, criminal proceedings due to social and legal conflicts in the field of security health and the commission of relevant offenses.

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