LEGAL ENFORCEMENT AND DEVELOPMENT DIRECTIONS OF HEALTH LAW IN UKRAINE

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ABSTRACT

Introduction

The development of medical law should take place systematically based on scientific basis and guided by international experience. The article describes the tendencies and prospects of the medical law development of Ukraine in the context of globalization and European integration processes.

The aim of this work is to investigate the problems of legal enforcement and directions of the medical law development in Ukraine

Materials and methods: we analyzed national and international acts that regulate community rights for medical care, protection of patient rights, which were studied using content analysis and analytical experience, as well as generalization of court practice and statistical data.

Review and Conclusions:

Violation of patient rights is a socially harmful act, impunity of which also affects social security. The quality control mechanism of medical care should be permanent and aimed at improving this quality. It is necessary to create a National Quality Control Agency that would be independent, not subordinate to the Ministry of Healthcare of Ukraine, with professional experts with experience in this direction. The problem of legal protection of patient and doctor rights, as well as provision of legal support to medical institutions and the creation of a regulatory framework to reform the health care system is relevant. It is necessary to create a register of medical lawyers. Creating a system for reporting and monitoring medical errors should be one of the priorities of health care reform in Ukraine.

Key words: medical law, rights of patients, knowledge of patients, right for health, health care quality, doctor error, control of medical reform quality, bioethics.

Introduction

Currently, the development of the conceptual framework for the development of medical law and bioethics in Ukraine continues. Perception of the reform of the medical industry in society is rather ambiguous. And not only from a social point of view, but also in view of the constitutional guarantee of free medical care. The human right to health care is stipulated in Art. 49 of the Constitution of Ukraine, according to which state and communal health care facilities are provided free of charge, for the most part, is not fulfilled. Especially in the sense of providing such assistance «to all citizens fully», as stated in the decision of the Constitutional Court dated May 29, 2002 № 10-rp/2002 [1]. Unfortunately, more and more cases are known when the rights of patient are violated by doctors and other employees of medical institutions. The lack of quality standards for health care, the closure of the medical community, the availability of paid and «shadow» medical services, illegal medical and pharmaceutical activities are the main reasons for abusive and medical errors. Protecting the rights of patient, assessing the pre-trial and judicial prospects of resolving conflicts between the patient and the medical institution (physician), reimbursement of health damage (moral harm), legal support of medical organizations (especially private ones) are only a part of the questions related to new branches of law - medical law and bioethics. Therefore, the concept of a global right to health care needs further legal research.

The aim of this work - to analyze the national and international legislation to ensure patient rights and to study the main tendencies of the development of medical law in Ukraine and foreign countries.

Materials and methods

We analyzed national and international acts regulating the rights of citizens to health care, the protection of patient rights studied using the content analysis and analytical experience, as well as generalization of judicial practice and statistics.

Review and discussion

Human rights have come to the fore in many fields of law. However, health is a basic social good and ensures effective health protection and the availability/accessibility of adequate health care is a basic responsibility of the state. Health law is instrumental in the realisation of that responsibility and therefore the right to health care is always engaged in health law [2].

In the modern legal system, the issue of care, protection, order of realization of the right to life, health and the right to personal safety is devoted to the norms of the constitutional, administrative, civil, criminal and other branches of the law of Ukraine. The lack of a single definition of the right to life in various approaches to the scientific understanding of the phenomenon proves the need to isolate the constituent elements of the right to life into a

separate component, in our case, in the block of medical reform [3]. The concept of «health protection law» (Health Law) is increasingly appearing in scientific circulation both abroad and in Ukraine, and receives more and more supporters. The substantive sphere of health-care law includes proper health law, pharmaceutical law and legal support for the functioning of the health care system [4, 164].

L. Gostin and A. Talor defines global health care as an industry that encompasses the legal rules needed to create the conditions for reaching the highest possible level of physical and mental health. This sector is intended to promote a behavior towards health care by key players that significantly impact public health including international organizations, governments, business structures, foundations, media, and civil society [5].

Today, there is no doubt that health law and bioethics should be developed. The legal regulation of relations in this area is very important for their development. Health law is characterized by the presence of a large number of normative legal acts in the form of the Constitution of Ukraine, the Laws of Ukraine and the number of subordinate acts. The basic legislative act in the health care field is the Law of Ukraine about «Fundamentals of the Ukrainian legislation on health care» (1993). Many issues are regulated by special laws, for example: the Law of Ukraine «On Medicines», the Law of Ukraine «On Psychiatric Aid», there are a large number of Decrees of the Cabinet of Ministers of Ukraine and a huge mass of Decrees of the Ministry of Health, National Services and Departments. All this, along with the specifics of the industry, creates difficulties in protecting the rights of both patients and healthcare workers.

The basic principle of medical reform in Ukraine is that the state begins to pay for the medical service provided to the patient, rather than financing the number of bed places in hospitals. This will allow you to wisely spend your medical budget - to send funds to those who really need help. This is the principle - the money goes for the patient [6].

The Law of Ukraine «On Amendments to certain legislative acts of Ukraine on the legislation improvement regarding the activities of health care institutions» dated April 6, 2017 № 2002-VIII (hereinafter - the Law) intoruduces financing of a family doctor field in the front-line medicine who has the right to conclude contracts with 2,000 patients. A doctor will receive a certain amount per year to your account for each contract. The law provides the implementation of a number of measures aimed at creating a network of state and communal medical institutions with a sufficient level of autonomy for effective and timely health care of the population; it resolves separate issues related to the contracts on populaton health care, which will be made in accordance with the special order approved by the Cabinet of Ministers of Ukraine [7].

The Law contains a provision that health care is provided free of charge (at the expense of budgetary funds) in health care institutions and individuals entrepreneurs who have received the corresponding license. And it is specified at once: only those whom the main spending unit manager made contracts on population health care with. There are further certain financial limitations: such contracts are made only within the limits of budget funds provided for health care for the relevant budget period based on the cost and volume of medical services, a customer of which are the state or local authorities. Therefore, in the absence of such funds, the amount of guaranteed health care will be limited and reduced - according to the «limits» of the budget. From an economic point of view - it is a rational and logical approach, but from the standpoint of medicine - a significant risk. After all, taking into account the inability to accurately predict the course of a patient's illness, his recovery etc, the introduction of normalized distribution of costs and the normalization of medical interventions hides the danger of uncertainty. Even the strict implementation of treatment protocols and regulatory funding on their basis can significantly limit the physician's ability to make flexible decisions about patient treatment and turn it from a logical thinking specialist to a purely technical performer [5].

In the modern world, health care quality is considered as the main target function of the health care system and at the same time the determining criterion of its activity. In many countries, quality assurance programs have been adopted and implemented that underpin national health policies. This is the lever that influences the development of medicine, and is determined by many components - the quality of management (purpose, goals, principles, methods, structure, organization, planning), organization of the process of providing health care and its resource support (material, technical, methodological, personnel, financial, etc), the implementation of technology, modern guidelines, standards, clinical protocols [6].

According to the order of the Ministry of Healthcare of Ukraine dated August 1, 2011 № 454 «On approval of the Concept of management of health care quality in the healthcare system in Ukraine for the period up to 2020», the principle of continuous improvement of quality is proclaimed in the state, the key component of which is a clinical audit. The Concept states: the current analysis of the results of the work of health care institutions is based on the accounting and reporting documents (statistics and annual activity reports) approved by the state authorities, as well as on the results of individual studies, which is not enough to assess the quality of health care and determine its improvement directions. [7].

The order of the Ministry of Healthcare of Ukraine dated 05.02.2016 № 69 «On the organization of clinical and expert assessment of the quality of health-care provision and health care» «modernizes» the expert assessment of the second and third groups of expertise that is carried out in case of patient death, divergence of determined diagnoses, non-compliance with

health care standards and health care, clinical local protocols, material and technical reports, as well as in cases that were accompanied by complaints from the applicant etc. Thus, although the modern quality control methods - clinical audit and monitoring are mentioned in the regulatory documents of the Ministry of Healthcare, in practice an expert assessment of the outcome and some unwanted cases is carried out using «organizational measures» to punish the perpetrators. While a clinical audit in a health institution is usually carried out once a quarter and is aimed at not penalizing individual workers for not achieving acceptable quality, but seeking opportunities to achieve it [8].

Effective quality control system of medical services provision is an important element in the implementation of the medical reform. The process by which the government grants permission to practice a practitioner or a health organization (usually after verifying compliance with minimum mandatory standards) is defined in the legislation as licensing. In Ukraine, licensing applies to all legal entities, regardless of their organizational and legal form, and individuals-entrepreneurs who conduct business activities in medical practice. If licensing guarantees minimum standards for patient safety and minimizes health risks, medical accreditation is intended to ensure continuous improvement of quality and aims at achieving optimal standards. The national accreditation body, through an independent external evaluation, publicly confirms the achievement of accreditation standards by one or another institution. For example, in the UK, this is the United Kigdom Accreditation Forum (UKAF), a volunteer network of NHS organizations that is accountable to the government; in France - HAS, a public health authority (an independent non-profit public scientific organization); in the United States, the Joint Commission on Accreditation of the Healthcare Organization (JCAHO, a national nonprofit organization). As in Ukraine, accreditation is carried out not by an independent structure, as is the case of most EU countries, but by the Ministry of Healthcare of Ukraine, which verifies subordinate institutions, it creates objective obstacles for ensuring the proper quality of medical care quality in health care [9].

The patient rights phenomenon is fundamental to modern law and medical ethics. The patient rights as a phenomenon, term and legal structure are derivatives of human rights to the extent that the patient is a person. The patient rights are inherent only to those who have the appropriate special legal status. Violation of the patinet rights is a socially harmful act, impunity of which also affects social security. Domestic legislation provides a whole range of patient rights (however, serious problems are often encountered when realizating these rights in practice), however, with some exceptions, it does not properly establish the patient responsibilities and responsibility for their failure [12]. According to M. Watad and R.

Grevtsova, «it is important that in attempts to resolve various relations related to human health, the patient, the very person for whom these relations arise, will not be forgotton about». An important instrument for ensuring this is the international health law, which has a human-centric orientation [13, 460; 14].

The basic legal document on the basis of which the concept of the patient rights is based is the Universal Declaration of Human Rights adopted by the General Assembly in 1948. On November 4, 1950, the Convention for the Protection of Human Rights and Fundamental Freedoms was signed. At the beginning of the 1990s, almost everywhere, the fundamental patient rights of the patient were recongized, which continue to evolve to date (the «Lisbon Declaration on Patient Rights» of 1981, the «Declaration on a Policy for the Enforcement of Patient Rights in Europe» of 1994, «The European Charter of Patient Rights» of 2002): the right to information on the diagnosis and prognosis of their own illness; the right to choose a doctor; the right to preserve the confidentiality of medical information; the right to privacy; the right to ensure the rule of informing the consent.

The «Concept of Patient Rights in Europe: General Provisions» document adopted by the who European Patients' Consultative Meeting (Amsterdam, 28-30 March 1994), played an important role in defining key provisions in patient rights. The list of patient rights in this document reflects the progressive trends of today and corresponds to the development of modern law and health care. The purpose of this document is to guarantee the protection of fundamental human rights and promote the humanization of assistance to all categories of patients including the most vulnerable, such as children, psychiatric patients, the elderly and severely ill. In essence, this reflects the desire of people not only to improve the quality of their received treatment and preventive care, but also to more fully recognize their rights as patients.

Due to the need to preserve human identity, to ensure respect for human dignity and the availability of a «bioethical dimension» of issues to be resolved by the legislator or the court, the impact of bioethics on the right to health is increasing. Some researchers point out the «bioethisation» of the legislation and the rights of foreign countries in certain sectors, for example, in the field of criminal law, and its necessity in Ukraine [15, 140-145].

One of the most acute problems is the consent of the patient to participate in a medical study (medical biologic experiment). On the one hand, there is a need to revise certain standards of research aimed at preventing abuse of consent, especially by consent of vulnerable persons (incapable or incapable adults, minors). On the other hand, strict regulation of research, the trend of which has been observed lately, may lead to a restriction of research, despite the great role they play in meeting the needs of society in health care services. According to J. Dangati,

it is now necessary to establish a balance between the protection of the rights of the subjects and the freedom to conduct research [16, 489].

At the same time, there is a problem of medical error, which is urgent not only for Ukraine. According to the European Commission «Special Eurobarometer» data (2006), 78% of EU citizens consider medical errors to be a serious problem. National legislation does not define the term «medical error». The legal doctrine ambiguously understands it too. A similar situation is observed in many developed countries. In the report, «Man is Fallible: Building a Healthier Healthcare», published by the Institute of Medicine (now the National Academy of Medicine of the United States) in 1999, a definition that had already become classical was proposed. According to it, the error is «the failure of the planned action to be carried out as expected, or the use of an erroneous plan to achieve the goal». In general, the prevailing view is that a doctor (or rather medical) mistake is an act or omission of a health professional who is characterized by good faith and does not contain evidence of a criminal offense. It is also believed that medical errors include acts that result in harm to the patient. Overseas, doctor (medical) mistakes were paid particular attention to at the turn of the 2000s. The above-mentioned report became a push. It showed that from 44 thousand to 98 thousand Americans die from medical errors every year. And this is much more than due to accidents or industrial accidents.

The study of the Johns Hopkins University Faculty of Medicine, published in 2016, confirmed that approximately 9.5% of Americans die from medical errors in the United States every year. According to the who, in most EU member states, medical errors and other adverse events are observed in 8-12% of inpatient care cases.

In 2006, the Committee of Ministers of the Council of Europe issued the recommendation Rec (2006)7 on patient safety management and prevention of adverse health events. Among the proposed measures, there is the development of a system for reporting incidents involving patient safety. In this case, the system should not be punitive. It should encourage healthcare providers and healthcare professionals to report such cases (if possible, the message should be voluntary, anonymous and confidential). Information about medical errors is also available from other sources, such as patient complaints registration system. In some European countries (Great Britain, Denmark, Ireland), such systems already exist. In many others, they are only being organized. Creating a system for reporting and monitoring medical errors should be one of the priorities of health care reform in Ukraine [17].

In 2017, Doctor of Medical Sciences V. Franchuk published a study on medical errors in Ukraine. Out of the 112 cases of medical care in the Ternopil oblast, the professor found errors in 92 of them (82.1%). Although in the same 2017, 91% of doctors in Ukraine were certified.

The high level of medical mistakes at a high level of qualification is connected with the corruption of the attestation system, - said O. Grishakov, a lawyer and managing partner of the law firm «Grishakov Law Company». At the same time, the qualification category does not mean that the doctor will be responsible. In Ukraine, there is simply no mechanism for prosecuting a specialist for incompetent provision of health care, said the lawyer [18].

Victimogenity of the absence of an effective criminal law response to the criminal misconduct of the patient rights is that, due to the systemic «blindness of the eyes» of the state authorities, the perception of the patient rights violation by doctors makes people believe that it is virtually impossible to bring the medical practitioner to criminal responsibility for committing a professional crime. Under such conditions, the patient, knowing that his rights are protected from medical arbitrariness, will not consider himself as a victim of the system and perceives a medical crime as a gift which he is «ready» for. In our opinion, the position of the necessity to meet the population social needs in the quality and safe provision of health care today is a radically different approach: without raising the role of the patient and shifting the attention of the state from the one who caused harm to the person who suffered from it, today, the criminal law will not get the trust of the society, which demands fair and proper satisfaction of its needs for proper legal guarantees of non-violation of human rights in Ukraine. Therefore, the proposal to supplement the Criminal Code of Ukraine with a norm that would include liability for the violation of patient rights by a medical or pharmaceutical worker that was known to such a worker could constitute or endanger the patient's life, health or reputation, is relevant [19, 136].

The practice of the European Court of Human Rights, which has touched upon a fairly wide range of bioethical issues (reproductive rights, the use of assisted reproductive technologies, assisted suicide, consent, for medical intervention, etc) [20] will play an important role in the search for legislative solutions to the problems within the right to health care, and also led to the spread of positive state obligations in the field of health raising the question about guarantees of health care, state responsibility for patient death and others [21, p. 15].

The issue of legal protection of patient and doctor rights, as well as provision of legal support to health institutions and the creation of a regulatory framework for reforming the health care system is relevant. As the Head of the Institute of Medical and Pharmaceutical Law and Bioethics of the Academy of advocacy of Ukraine R. Grevtsov states, in each region of the country, 40-80 civil cases are considered annually in the courts for compensation of property damage and moral damage caused to health due to providing health care of inadequate quality. However, there are not many lawyers who are capable of performing these tasks effectively. Among the important tasks faced by Ukrainian scholars, there is the study and generalization

of judicial and investigative practices on "medical" cases, which was recognized as one of the areas of health law development of Ukraine, the creation of a register of lawyers in health law [22, 11].

CONCLUSIONS

1. The quality control mechanism of health care should be permanent and aimed at improving its quality. It is necessary to create a National Quality Control Agency that would be independent, not subordinate to the Ministry of Healthcare of Ukraine, staffed by professional experts with experience in this field.

2. The modern medical system, which can be described as a model of technocratic type, is not ready for an independent solution to a number of problems that affect a human as a person, his rights and freedoms. One of the fundamental problems of modern law and medical ethics is that health care should be a human right, and not a privilege for a limited number of people who are able to afford it. Violation of patient rights is a socially harmful act, impunity of which also affects social security.

3. The problem of legal protection of the patient and doctor rights, as well as legal support of health institutions and the creation of a regulatory framework for reforming the health care system is urgent. However, there are not many lawyers who are capable of performing these tasks effectively. It is necessary to create a register of health lawyers.

4. The establishment of a system for reporting and monitoring medical errors should be one of the priorities of health care reform in Ukraine.

5. Among the areas of health law development in Ukraine, there may be indicated: development of a generally accepted concept of health law of Ukraine; formation and recognition of health law as an independent branch of law and legal science; development of the concept of improveming Ukrainian legislation in the field of health care, including adoption of the Medical Code of Ukraine; study and generalization of judicial and investigative practice on «medical» cases; development of practical recommendations for the subjects of health law; methods of protecting the rights and legitimate interests of patients, health workers and health care institutions, tactics and methods of conducting «health» cases.

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