PRACA POGLĄDOWA REVIEW ARTICLE

LEGAL REGULATION OF PROFESSIONAL OBLIGATIONS OF PHYSICIANS IN UKRAINE

Yuriy Baulin¹, Borys Rohozhyn², Inna Vyshnevska¹

¹YAROSLAV MUDRYI NATIONAL LAW UNIVERSITY, KHARKIV, UKRAINE ²KHARKIV MEDICAL ACADEMY OF POSTGRADUATE EDUCATION OF THE MINISTRY OF HEALTH OF UKRAINE, KHARKIV, UKRAINE

ABSTRACT

Introduction: It was identified that one of the priorities of medical reform in Ukraine is the establishment of an effective system of legal regulation of professional physician's obligations that meets European standards. However, the legal regulation of relations between actors in the field of health care lags behind the practice of their development. The aim to find out the status of legal regulation of the professional obligations of health workers, to identify the gaps in this regulation, to formulate proposals for improving the legal framework for the issue under investigation.

Materials and methods: Legislation of Ukraine and certain European countries, international declarations and conventions, scientific works, 28 judgments of the European Court of Human Rights, 96 sentences of the practice of the national courts of Ukraine.

Conclusions: During the study, the stages of determining the professional physician's obligations were singled out, which would optimize the legislative process of regulation of obligations. One of the problems is the incorrect translation of protocols, which is assigned to a medical care institution. It was proposed to solve this problem by introducing a unified system of protocols and standards, the duty of translation and adaptation of which is entrusted to the central body of executive power in the field of health care. It is relevant to consolidate the duty of medical records management at the level of law, which will serve as a guarantee of ensuring the proper performance by the physician of a professional obligation to treat and diagnose a particular patient. In order to avoid cases of judgments, based on the results of the commission's assessment of the actions of a physician and to eliminate the number of cases of unjustified attraction of physicians to liability, it is necessary to consolidate a clear list of general professional physician's obligations in a single regulatory act.

KEY WORDS: medical law, physician, professional obligations

Wiad Lek 2019, 72, 9 cz II, 1839-1843

INTRODUCTION

The structural transformation of the health care system in Ukraine was initiated by the adoption by the Verkhovna Rada of the Law of Ukraine "On State Financial Guarantees for the legal and regulatory framework for governing the activities of physicians. In particular, the implementation of market relations caused significant changes in the interaction of patients, the state, medical institutions, namely, health-care providers and medical personnel, who offer medical services.

At the time of the medical reform in Ukraine in 2018, the autonomization of the primary health-care was implemented and a new list of primary health-care services and new requirements for the equipment of primary health-care services were approved.

However, the legal regulation of relations between actors in the field of health-care and, accordingly, the formalization of these relations substantially lags behind the practice of their development. This may be the basis for legal and social conflicts in the provision of health services.

The need for a high-quality legal regulation of the professional obligations of a health worker in Ukraine needs clear and precise legal regulation. Taking into account the path of Ukraine to the European Union, the experience of European countries in this area requires the bringing of Ukrainian national legislation to EU standards.

THE AIM

To find out the status of legal regulation of the professional obligations of health workers, to identify the gaps in this regulation, to formulate proposals for improving the legal framework for the issue under investigation.

MATERIALS AND METHODS

Laws of Ukraine, orders of Ministry of Health of Ukraine, legislation of certain European countries, Declaration of Helsinki of the World Medical Association (hereinafter -WMA), the Universal Declaration of Human Rights and Bioethics, the European Convention on Bioethics and Human Rights, scientific works, 28 judgments of the European Court of Human Rights, 96 sentences of the practice of the national courts of Ukraine.

This article is based on dialectical, comparative, analytical, formal-logical, statistical and complex research methods.

REVIEW AND DISCUSSION

1. Provision of quality medical services is one of the most important components of a full-fledged life of society, which is why the activities of the doctor are subject to clear legal regulation. An analysis of the existing regulatory framework governing health-care services makes it appropriate to draw the conclusion that legal regulation covers the period from the training of a medical student to the direct provision of medical services as a doctor. This period can be divided into the following stages, which are subject to legal regulation: 1) acquiring the status of a doctor; 2) the admission of a physician to the provision of medical services; 3) establishment of professional obligations of a doctor; 4) the implementation of commitments by a doctor; 5) the responsibility for the non-implementation of the doctor's professional obligations. This article examines the stage of legal regulation of the establishment of professional obligations of a doctor.

The synthesis of 96 court's decisions regarding the non-provision of health-care to a sick person by a medical worker and improper fulfillment or non-fulfillment of professional obligations by a medical worker revealed that the main violations in the professional activity of a doctor are: 1) the absence of a corresponding certificate of a specialist physician in providing health-care services; 2) non-fulfillment of the professional obligation imposed on a doctor in providing health-care services; 3) delay and untimely provision of health-care services; 4) incorrect assessment of the patient's condition, which led to serious consequences in the form of deterioration of the patient's health or death; 5) the inattention of a physician during medical procedures or rapid medical intervention; 6) failure to comply the requirements of the standards and treatment protocols of diseases; 7) filling in the documentation regarding the state of health of a patient in violation of the requirements.

An analysis of the court practice has revealed that the violation of the standards for providing health-care services and job descriptions by a doctor is most common. As an example, the verdict of Cherkasy court can be mentioned, which found guilty an anesthesiologist of improper performance of professional obligations, which led to the death of the patient. During the resuscitation, the anesthesiologist did not carry out careful monitoring of the patient's condition and, due to his careless attitude to his professional duties, introduced into the body of the patient «Lidocaine», the introduction of which was not foreseen at that stage of treatment, which caused the death of the patient [2].

The overcoming of the problems that are currently taking place in the provision of medical care services by a doctor requires a clear definition in the national legislation of the professional obligations of a medical worker.

2. To apply for a doctor's post and to provide medical services in the future can a person, who has medical education, finished the internship and received a certificate of a specialist doctor. Following the implementation of these requirements, a person receives the right to practice medical activity by concluding an employment contract, in which one of the main conditions is the determination of the responsibilities of the medical officer, which are divided into general and special professional obligations.

G. Alcheva notes that the rights of patients and doctors are interdependent and give rise to obligations on both sides. This particular conformity of the rights and duties of doctors and patients supports the provision of medical care of the proper quality [3, p. 22].

General professional duties are mandatory for all doctors, regardless of their specialization, and provided for by national regulatory legal instruments and international instruments, namely: 1) by the laws of Ukraine, for example, the Fundamentals of Health Legislation of Ukraine (hereinafter - Fundamentals); «On Emergency Medical Aid», etc.; 2) by the international instruments, namely: the Lisbon Declaration on Human Rights, etc.; 3) by the subordinate regulatory legal instruments (decisions of the Cabinet of Ministers of Ukraine, orders and instructions of the Ministry of Health of Ukraine, etc.); 4) by the local regulatory legal instruments - acts adopted at the level of a medical institution.

The Lisbon Declaration on Human Rights and in the Clause 4 of the Helsinki Declaration of the WMA establish the basic principles of the work of the doctor, which should be aimed at supporting and protecting the health of a patient, taking into account the legal, ethical and practical norms of the country in which a doctor practices the medical activity [4, 5].

The International Code of Medical Ethics of the WMA divides professional duties of the doctor into general, concerning sick and in relation to others. According to the Code general responsibilities are as follows: to adhere the highest standards of professional activity; to provide competent medical aid with full technical and moral independence, etc.

The professional obligation of a physician for patients are as follows: to provide the patient with all the resources of his or her science; If the doctor is unable to conduct an examination or treatment, he must engage another physician, who has such facilities; to guarantee medical confidentiality and a number of other responsibilities.

The list of duties of the physician in relation to others includes the regulation of the relationship between doctors in the exercise of their professional activities and the obligation to adhere to the principles of the Geneva Declaration, adopted by the General Assembly of the WMA [6]. To a certain extent, these responsibilities have found their consolidation in the Fundamentals [7].

3. Particular attention should be paid to the professional obligation, holding any medical intervention with the implementation of professional requirements and standards, which is enshrined in Art. 4 of the Convention on the Human Rights and Dignity in connection with the Application of the Achievements of Biology and Medicine [8].

This obligation is enshrined in the Methodology for the development and implementation of medical standards of medical care on the principles of evidence-based medicine, which states that in the absence of a unified clinical protocol in the national system of standards, a health worker must apply a new clinical protocol if it is translated into Ukrainian and approved by the Ministry of Health. If the protocol is set out only in English then its choice, translation and application are carried out in accordance with the order of the medical institution [9].

Analyzing the above-mentioned legislative provision, it is possible to distinguish several issues that arise in medical officers when establishing and fulfilling this duty. New clinical protocols are often not adapted for use in Ukraine, since there are difficulties with the use of medicine or their components when treated under a new protocol due to their absence on the territory of Ukraine. The same applies to technical support for the use of new methods and methods of treatment, since the level of technical equipment of health facilities in most areas is quite low. These circumstances may threaten the proper use of new protocols without their prior adaptation to Ukrainian realities.

When analyzing a medical error, O. Gornostay and other scientists note that one of the most important professional duties of a doctor is the implementation of protocols and standards for the provision of medical care, but the implementation of this duty in practice is complicated by the lack of translations of international protocols and standards; by the politicization and ideologization of national protocols, and by the primitivism of local protocols [10, p. 880].

Taking into account the experience of health care systems of foreign countries, it seems appropriate to create a regulatory framework that would include a system of quality assurance of medical care, an important element of which is the approval and implementation of national quality standards for medical care.

4. A medical officer's obligation is important in order to provide the patient with accessible information about the state of health, the purpose of medical treatment and the forecast of the possible development of the disease, in particular the risk to life and health. This duty is also enshrined in Art. 9 of Helsinki Declaration of the WMA, Art. 39 of Fundamentals, paragraph 3.6. The Ethical Code of the Doctor of Ukraine and other regulatory legal instruments.

Such violations became subject for consideration by the Constitutional Court of Ukraine, which in its decision noted that medical information in its legal regime belongs to confidential information, which the doctor is obliged not to disclose. However, there is an exclusion from this obligation, namely, the physician is obligated to provide such information in full and in an accessible form at the request of a patient, his family members or legal representatives [11].

The European Court of Human Rights assesses the refusal to provide the patient with medical records regarding his health as a violation of Art. 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms. An example of the jurisprudence on this issue is the decision of the ECHR «K.N. and others against Slovakia». When establishing violation of Art. 8 of the Convention, the Court noted that the State has a positive obligation on the granting a person access to the documentation and records relating to the state of his or her health. The state is obliged to provide conditions for the copying of documents containing personal data, or, as appropriate, to provide compelling reasons for the refusal of such copying [12]. 5. It is mandatory to obtain patient consent for any medical intervention for preventive, diagnostic or therapeutic purposes, which is enshrined in Article 6 of the Universal Declaration of Human Rights and Bioethics[13]. The mentioned professional duty of the doctor was embodied in Art. 43 of Fundamentals. As an exclusion from this rule, the article stipulates that consent of the patient is not required in the case of presence of signs of a direct threat to the patient's life, provided that it is impossible to obtain consent for such an intervention from the patient or his legal representatives for objective reasons.

M. Pashkovska notes that during the provision of medical services, some doctors violate the requirements for obtaining consent of the patient. Such violations are that: 1) doctors provide individual medical services without the consent or with consent of an incapacitated or partially capable person; 2) the consent is formalized without complying with the formal requirements; 3) the consent was given long before the provision of medical services, without proper informing of the patient about the order of providing such services or about the potential risks and consequences; 4) the consent was not given by the person voluntarily [14, c. 1241-1242].

In the decision of «M.A.K. and R.K. against the United Kingdom», the ECHR found the violation of Art. 8 of the Convention for the conduct of medical examination, blood sampling for the analysis and implementation of photo fixation of the wound of the child without the consent of the parents, as required by national law. Taking into account the circumstances of the case, the Court did not establish any justification because it was decided to take a blood test and make personal photos of a nine-year-old girl, contrary to the clearly expressed will of both of her parents, while she was in the hospital alone [15].

6. The timely and proper filling (registration) of the medical card of the patient is also one of the general professional obligation of the doctor. The experience of consolidation such a duty at the regulatory level exists in Germany, where, in accordance with Clause 2 § 630f of the German Law on Patient Rights, it is foreseen that the physician who carries out the treatment of the patient is obliged to record in the patient's medical card all measures, processes and results, in particular, anamnesis, diagnosis, examination, results of examination, therapies and their consequences, interventions and their consequences [16].

In Ukraine, this obligation is enshrined in the Instruction on filling in the form of primary records «Medical card of the in-patient» [17]. Pashhkovskaya notes that the medical records that the physician records during the patient's treatment is one of the main evidence in the litigation against the doctor. That is why the doctor is obligated to keep records in compliance with the legal form and in accordance with the requirements of the law [18, p. 1621].

It is relevant to consolidate this obligation at the level of the law, since medical records are important in the provision of medical services to the patient, and is one of the guarantees of the proper implementation of the doctor's professional obligation to treat and diagnose a particular patient. A prime example of the use of medical records as an evidence in criminal proceedings can be the verdict of Berdychiv City Court. The surgeon focused only on the disease of the lower extremities and did not pay attention to the physical state of the patient's health, namely, heart disease, which led to the death of the patient during treatment. During the inspection, it was discovered that the surgeon did not perform a daily review of the patient and did not fulfill the medical documentation. Taking into account the circumstances of the case, the court found the surgeon guilty of improper performance of professional duties and sentenced him to deprivation of the right to practice medical activity for 4 years [19].

On the basis of the human right to proper medical care, N. Gutorova, O. Zhitniy and O. Solovyov single out such a duty of the doctor as the use of safe and high-quality medicine in the provision of medical care, which is one of the obligatory components of an effective system of health protection I [20, p. 856].

7. Taking into account that the general professional duties of doctors in Ukraine are enshrined in normative legal acts of various legal force, in order to ensure legal certainty in the conduct of medical activities, it is relevant to establish in the Fundamentals an exhaustive list of professional duties of a medical officer, which include the following: 1) to contribute the protection and strengthening of human health, prevention and treatment of diseases, provide timely and high-quality medical care; 2) to provide appropriate emergency medical care to citizens in the event of an accident and other extreme situations free of charge; 3) to carry out medical activities in accordance with the received certificate of a specialist doctor; 4) to conduct timely and qualified examination and treatment of the patient in accordance with the standards, instructions and protocols of diagnosis and treatment; 5) to explain to the patient in an accessible form the state of his health, the purpose of the proposed research and medical measures, a forecast of the possible development of the disease, including the existence of a risk to life and health; 6) to obtain the consent of the patient for medical intervention for preventive, diagnostic or therapeutic purposes; 7) to provide medical care in full to a patient who is in a state of danger to life; 8) to record the state of health and medical treatment of the patient, reflect the changes in the patient's condition (deterioration, improvement, complete recovery) and the whole process of medical treatment or rehabilitation during receiving inpatient care; 9) to adhere to the requirements of professional ethics and deontology, to keep confidential information, except the cases stipulated by the legislative acts, which became known in connection with the performance of professional or official duties about the disease, medical examination and its results; 10) to increase the level of professional knowledge and skills constantly, to study new methods of treatment; 11) to provide advisory assistance to the colleagues and other health care workers; 12) to disseminate scientific and medical knowledge among the population, to promote a healthy lifestyle.

8. Special professional obligations of a doctor are such obligations, the exhaustive list of which is individual-

ized for each doctor depending on his specialty and the specific position he or she occupies in a medical institution. The list of special professional duties of a doctor of a certain specialty is provided by subordinate and local acts. In particular, these include the orders of the Ministry of Health of Ukraine regarding certain types of medical activities, as well as job descriptions, which specify the professional obligations of a specialist doctor on his or her position. By a guide to the qualification characteristics of professions of medical workers was established requirements for the level of knowledge of the specialist doctor, his or her tasks and responsibilities and qualification requirements [21].

CONCLUSIONS

Creation of an effective system of legal regulation of professional physician's obligations that meets European standards is one of the priority directions of improvement of Ukrainian legislation in the field of health-care services.

The systematic approach to the legal regulation of the professional obligations of health-care officers makes it possible to balance public interest in the provision of high-quality treatment and the individual interest of a physician who is interested in clearly defined professional obligations.

According to the results of the analysis, the imperfect regulation of the procedure and standards of the provision of medical care and the lack of proper regulation of the physician's professional obligations not only impair the quality of the provision of medical services, but also lead to the unjustified attraction of the physician to liability.

In order to solve these problems, it is necessary, to systematize health-care service legislation, to establish a clear list of general professional obligations of the physician and criteria for the quality of the provided medical care, which can allow to avoid subjectivity in evaluating the actions of the physician during the provision of medical care services and will reduce the number of cases of unjustified attraction of physicians to liability.

REFERENCES

- 1. On State Financial Guarantees of Public Health Care: The Law of Ukraine as of January 30, 2018 [Electronic resource]. it is access Mode: https:// zakon.rada.gov.ua/laws/show/2168-19
- 2. Sentence of Cherkasy District Court in case no. 2320/1119/12 dated 09/10/2012[Electronic resource]. it is access Mode: http://www.reyestr. court.gov.ua/Review/25908221
- 3. Gabriela Alcheva et al.: Implementation of patients' rights legislation in the republic of macedonia: gaps and disparities. Health and human rights, 2013. volume 15, no. 2: 20-31
- 4. Lisabon declaration about human rights 34th the World medical assembly from 01.10.1981 [Electronic resource]. it is access Mode: https://zakon.rada.gov.ua/laws/show/990_016
- 5. Helsinki declaration of the World medical association is "Ethic principles of medical researches with participation of man in quality of research: object" by the state on 01.10.2008 [Electronic resource]. it is access Mode: https://zakon.rada.gov.ua/laws/show/990_005

- 6. An international code of medical ethics of the World medical association is from 01.10.1983 [Electronic resource]. it is access Mode: https://zakon.rada.gov.ua/laws/show/990_002
- 7. Bases of legislation of Ukraine about a health protection : Law of Ukraine by the state on January, 01, 2019 [Electronic resource]. it is access Mode: https://zakon.rada.gov.ua/laws/show/2801-12
- 8. Conventions about the protection of rights and dignity of man in connection with application of achievements of biology and medicine from 16.12.1996 [Electronic resource]. it is access Mode: https://zakon. rada.gov.ua/laws/show/994_334
- 9. About creation and introduction of medical and technical documents from standardization of medicare in the system of Ministry of health Ukraine : order of Ministry of health Ukraine from 28.09.2012 № 751 [Electronic resource]. it is access Mode: https://zakon.rada.gov.ua/laws/show/z2001-12
- Alesia Gornostay, Alona Ivantsova, Tetiana Mykhailichenko, Medical error and liability for it in some post-soviet countries (belarus, kazakhstan, moldova, ukraine) Wiad Lek 2019, 72, 5 cz. I, 877–882
- 11. Decision of Constitutional Court of Ukraine №18/203-97 from 30.10.1997 [Electronic resource]. it is access Mode: https://zakon.rada. gov.ua/go/v005p710-97
- 12. Case of K.H. and other against Slovakia, decision of the European Court of Human Rights from 28.04.2009 [Electronic resource]. it is access Mode: http://www.pravosudie.biz/353486
- 13. General declaration is about human rights and bioethics from 19.10.2005 [Electronic resource]. it is access Mode: http://www.un.org/ ru/documents/decl_conv/declarations/bioethics_and_hr.shtml
- 14. Paszkowska Małgorzata Podstawowe standardy prawne wykonywania zawody lekarza Wiad Lek 2018, 71, 6 : 1239-1244
- Case of M.A.K. and R.K. v. the United Kingdom: decision of the European Court for the rights of the people from 23.03.2010 [Electronic resource]. it is access Mode: https://www.echr.coe.int/Documents/Research_ report_bioethics_RUS.pdf
- Patientenrechtegesetz [Електронний ресурс]. Режим доступу: https://www.bundesaerztekammer.de/recht/gesetze-undverordnungen/patientenrechtegesetz/
- 17. Instruction in relation to the fill-out of primary registration documentation № 003/oh the "Medical map of in-patient №____": Order of Ministry of health Ukraine from 14.02.2012 № 110 [Electronic resource]. it is access Mode: https://zakon.rada.gov.ua/laws/show/z0662-12

- Paszkowska Małgorzata, Prawo pacjenta do dostępu do dokumentacji medycznej a lekarski obowiązek jej udostępnienia Wiad Lek 2018, 71, 8 : 1621–1627
- Sentence of Berdichevsky city court of Zhytomyr region in case number 1-39 / 10 of January 28, 2009 [Electronic resource]. it is access Mode: http://www.reyestr.court.gov.ua/Review/44668540
- Nataliya Gutorova, Oleksandr Zhytnyi, Oleksii Soloviov, Falsification of MEDICAL products: criminal law mechanism combating threats to public health Wiad Lek 2019, 72, 5 cz. I, 856-861
- 21. Reference book of qualifying descriptions of professions of workers. Producing 78. A health protection : is by the state on 12.07.2018 [Electronic resource]. it is access Mode: https://zakon.rada.gov.ua/rada/ show/va117282-02

Authors' contributions:

According to the order of the Authorship.

Conflict of interest:

The Authors declare no conflict of interest.

CORRESPONDING AUTHOR Yuriy Baulin

The Department of Criminal Law Yaroslav Mudryi National Law University, Kharkiv, Ukraine Pushkinskaya str., 77, 61024 Kharkiv, Ukraine tel: +380951406024 e-mail: innavish12@gmail.com

Received: 12.05.2019 Accepted: 28.08.2019