DISCLOSURE OF THE ESSENCE OF POLITICAL INSTITUTIONS
THROUGH THE PRISM OF THE ORGANIC APPROACH

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During the periods of social transformation, the role of political institutions in implementation of necessary changes becomes especially topical. The significant number of approaches in the social sciences to this concept is often causing misunderstanding such phenomena as a political institution, its place and role in our life and the whole life of society. On the basis of the organic approach, there are three main criteria of a political institution in modern society formulated. It is disclosed that all public institutions, including political ones, consist of three basic elements. There is approved the influence of individuals on the formation of political institutions, in particular, in the context of their reform.

Key words: political institutions, public institutions, organic approach, organelles, nervous system, state, model, social relations.

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**LICENSING OF ECONOMIC ACTIVITY
IN UKRAINE HEALTH CARE SYSTEM**

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The article substantiates the complex nature of the legislation in the sphere of regulation of medical practice activity that includes the rules of various branches of law, which at the same time are connected with the same subject of legal regulation. It shows the role of licensing as a main instrument of medical practice activity regulation – the kind of economic activity in the sphere of health care that is provided by the entities exclusively on the basis of a license obtained according to the law and implies the provision of medical care and medical services aimed on the realization of human rights regarding the protection of their health as the highest social value. In the article there are results of the analysis of the regulative and legal ensuring of licensing process of economic activity in the modern system of health care of Ukraine.

Key words: economic activity; health care system; licensing.

Introduction. By ratifying the Association Agreement between Ukraine, on the one hand, and the European Union, the European Atomic Energy Community and their member states, on the other hand, Ukraine has received an instrument and a guide for its transformations.

The Strategy for Sustainable Development «Ukraine 2020» [15] defines the purpose, the vectors of the movement, the road map, the main priorities and indicators of the proper conditions for the formation and development of Ukraine.

Taking into account the strategic goal of Ukraine – the introduction of European standards of life in Ukraine [15], it should be noted that the most important principle of developing the European social space is recognition of a person as the highest value. Accordingly, the processes of society development in Ukraine should be based on the principles of European values, which require the establishment of effective mechanisms aimed at ensuring human rights.

The transformational processes in the national health care system have led to radical changes at all levels of its organization, greatly expanded the field and filled the medical practice activity with a new content. Therefore, the issue of licensing as the main tool for regulating economic activity in medical practice is relevant for modern Ukraine.

The analysis of recent publications showed that certain issues of legal regulation in the health care system of Ukraine, and in particular licensing, were investigated by M. M. Bilynskaya, Y. F. Radish, N. P. Yarosh, A. V. Khudoshina, G. M. Ursol, O. A. Skrypnik, O. M. Vasilenko and others. At the same time, the issue of licensing of economic activity in the health care system of Ukraine is still not sufficiently developed, in particular, taking into account the latest changes taking place in the field of health care.

That is why the **purpose of this article** is to highlight the analysis of regulatory and legal provision of the economic activity licensing process in the modern health care system of Ukraine.

Main part. The Constitution of Ukraine refers the health of the person to the highest social value in the state, the right to health care and medical care is guaranteed for everyone [2, art. 3, 49].

In the Fundamentals of Ukrainian Legislation on Public Health [4, art. 33] it is stated that medical care is provided according to medical certificates by professionally trained medical staff being in labor relations with health care institutions providing medical care according to the license received in accordance with the law, and individual entrepreneurs that have been registered and received the relevant license in accordance with the procedure established by law, and may be with these institutions in relations regulated by civil law.

People's healers who do not have special medical education are obliged to carry out their activities as individual entrepreneurs, while they do not have any relation to the provision of medical care. The question of engaging in folk medicine is regulated [4, art. 74] and requires obtaining a special permit for a term of 5 years.

Medical care is divided into separate types, including emergency, primary, secondary (specialized), tertiary (highly specialized), palliative [4, art. 8], and may also be provided in the form of medical rehabilitation. Medical care is aimed at prevention, diagnosis, treatment and rehabilitation in connection with illnesses, injuries, poisonings and pathological conditions, as well as in connection with pregnancy and childbirth [4, art. 3].

Health care institution in accordance with [4, art. 3] is considered to be a legal entity of any form of ownership legal form or its separate subdivision, which provides medical care to the population on the basis of the relevant license and the professional activities of medical (pharmaceutical) employees. According to Art. 16 [4] the health care institution carries out its activity on the basis of the statute (regulation), which is approved by the owner of the institution (a statutory body authorized by him).

Note: the provision that the conduct of economic activity in the sphere of medical practice is allowed only if the license has been obtained is fixed in the Law of Ukraine "Fundamentals of the legislation of Ukraine on health care" [4, art. 17], as well as in the Law of Ukraine "On Licensing of Economic Activities" [14], which in accordance with clause 15 part 1 of Art. 7 refers medical practice to the exclusive list of types of economic activities subject to licensing.

Licensing conditions for the conduct of economic activity in medical practice are defined by the Cabinet of Ministers of Ukraine (CMU). It should be noted that

the adoption in 2016 of a new decree “On approval of licensing conditions for the conduct of economic activity in medical practice” [7] was caused by the need for deregulation of entrepreneurial activity in the healthcare sector as well as the need to improve the medical care of the Ukrainian people. At the same time, it should be noted that with the adoption of this resolution [7] there was a conflict of law, when the License conditions for the conduct of economic activity in medical practice were at the same time in two versions: approved by the Order of the Ministry of Health of Ukraine (MoH) on February 2, 2011 No. 49 [8] and the Resolution of the Cabinet of Ministers of Ukraine dated March 2, 2016, No. 285 [7]. The situation arose as a result of the decision that the Cabinet of Ministers did not oblige the MoH to cancel the order (its cancellation took place later, on January 09, 2018, with entry into force [12]).

In our opinion, the positive moment when the CMU Decree came into force [7] was a reduction of the amount of data that is required to be declared by the entity to obtain a license and reduction of the list of documents that need to be added to the application for obtaining a license. Also, the use of European approaches should be noted in the implementation of a number of provisions aimed at providing opportunities for the development of public-private partnership, private medical sector, improving the quality of medical services and bringing them closer to the population.

The novelty [7] was in opportunity to open medical practice for individuals who do not have medical education, but provided they hire employees having medical education. The introduction of this rule was aimed, first of all, at creating conditions for attracting investment and expanding access to medical care in the least prestigious regions. Withdrawal of the requirement of binding an individual entrepreneur to get the highest qualification category in the corresponding specialty gives him the right to create jobs and hire doctors of the relevant specialties. Consequently, such person does not personally provide medical services, but exclusively conducts economic activity and is an employer for persons with the appropriate medical qualification. Under the condition of performing a personal medical practice, such a person is brought to responsibility.

An important rule [7] in ensuring the quality of medical practice was the consolidation of standards regarding the quality of medical care provided to patients in accordance with the standards and protocols approved by the Ministry of Health of Ukraine.

In the framework of our study, let's take a closer look at the process of obtaining a license.

In compliance with the Law of Ukraine “On Licensing of Economic Activities” [14], the CMU Decree [9] was approved, where the list of licensing bodies, in particular, the Ministry of Health was appointed as an executive body that carries out licensing of medical practice activity. Note, that in the structure of the Ministry of Health, this function is implemented by the Licensing and Medical Care Quality Control Agency, which includes the Licensing, Certification and Accreditation Division, and Medical Care Quality Department [16].

To obtain a license, in accordance with [14, Part 1 of Art. 10], the subject of economic activity has the opportunity to submit documents in different ways on his own choice: 1) personally; 2) by post; 3) electronically using the portal of electronic services for legal entities, individual entrepreneurs and public organizations.

Considering applications and taking decisions on the issuing, re-registration and revocation of a license is the function of Licensing Commission of the Ministry of Health of Ukraine at its meeting (based on [10]). The decision of the Commission is formalized by a protocol, which is the basis for the approval of the order of the Ministry of Health on medical practice licensing, which results in issuing license for the activity subject.

To obtain a license, the licensees in accordance with [7] must comply with *organizational, personnel and technological* requirements.

- According to *organizational* requirements, medical practice is conducted
- by medical specialties and specialties of junior specialists with medical education, the list of which is approved by the Ministry of Health;
 - by type of medical care (emergency, primary, secondary (specialized), tertiary (highly specialized), palliative, medical rehabilitation);
 - by the place (places) of its providing, which are indicated in the application for obtaining a license and in the documents attached thereto (taking into account the changes made by the licensee to the licensing authority).

Business entity that is a health care institution must have the following documents approved in accordance with the procedure established by law: the charter of the health care institution or the provisions of health care institution (depending on the legal form); staff list; provisions on its structural units (in particular, branches); job descriptions of employees; the internal regulations of the health care institution; local protocols (patient cards) in accordance with clinical protocols and standards of medical care (medical standards) approved by the Ministry of Health, or act on the basis of unified clinical protocols approved by the Ministry of Health.

It is also necessary to pass the accreditation of the health care institution in accordance with the procedure established by the Decree of the Cabinet of Ministers of Ukraine dated July 15, 1997 No. 765 [11]. At the same time, it should be noted that the name of the health care institution should correspond to the name in the list of establishments approved by the Ministry of Health and/or other central executive body.

Also, we draw attention to the fact that [7] defines the requirements to the licensee for disclosure of information about the institution and services, ensuring conditions for free access to service users, the availability of necessary documentation on licensing and equipment, etc. Requirements for keeping statistical documentation and ensuring control over the services are singled out. Regardless the form of ownership, the requirement to provide appropriate emergency medical care free of charge to people in the event of an accident and in other extreme situations is established. By complying with the legislation on the protection of personal data and medical secret, the subjects of medical practice activity fully and unconditionally ensure compliance with its regulations.

A separate group of requirements for the licensing of economic activities in the sphere of medical practice refers to the *personnel* aspect.

Thus, according to [7, p. 24], medical care should be provided by persons meeting the uniform qualification requirements approved by the Ministry of Health. These requirements are confirmed by the relevant documents of state or established standard. The head of a health care institution should be a person who meets the same qualification requirements [7, p. 28].

There are also requirements for the professionalism of personnel who for some time did not work by the specialty. In particular, doctors who do not work for more than three years on a particular medical specialty are allowed to conduct medical practice in this specialty after undergoing internship in accordance with the procedure established by the Ministry of Health [7, p. 29].

Personnel issues of individual entrepreneurs activity in accordance with [7, p. 34] are defined as follows: an individual entrepreneur has the right to employ doctors in accordance with the declared specialty, and junior specialists with medical education – depending on the profile (specialty) provided, that their qualification level corresponds to the uniform personnel requirements approved by the Ministry of Health. Individual entrepreneurs from among the junior medical specialists carry out medical practice independently or under the guidance of a doctor.

Technological requirements include the use by the licensee of medical products and devices only in adapted premises, the requirements of which are fixed in the instructions for use (passport) or technical documentation; as well as for functional purposes and in accordance with the requirements specified by the manufacturer in the instructions for use (passport) or technical documentation [7, p. 36].

Consequently, the licensee must comply with the detailed organizational, personnel and technological requirements, and the subject of economic activity in the field of medical practice should strictly adhere to them.

Note, that the effect of these licensing conditions applies to all legal entities, irrespective of the legal form of organization, and individual entrepreneurs who carry out business activities in the sphere of medical practice, except for those who carry out business activities related to the implementation of judicial and medical histology, forensic medical examination, forensic medical immunology, forensic medical criminalistics, forensic medical toxicology, forensic medical cytology, forensic psychiatric examination.

As a subject of licensing of economic activity in the sphere of medical practice the Ministry of Health verifies the submitted materials and takes a decision within three working days on the basis of receiving an application for obtaining a license. The reason for leaving the application without consideration is: submission of incomplete set of documents; improper registration of documents; non-observance of the terms of documents submission; the absence of information about the licensee or the availability of information about the state registration of its termination in the Unified State Register of legal entities and individual entrepreneurs.

Reasons for refusal to issue a license are: the applicant's unconformity with the established license conditions; unreliability of the data in the submitted documents or their divergence with the actual state of the entity.

The licensee acquires the right to conduct economic activity in the sphere of medical practice since the data entry into the Unified State Register of legal entities and individual entrepreneurs.

The license is issued in electronic form by entering a record into the specified register or in paper form in accordance with the order of the Ministry of Economic Development and Trade of Ukraine and the State Regulatory Service of Ukraine dated by July 14, 2015 No. 781/38 [13].

It should be noted that the license for the conduct of economic activities in the sphere of medical practice is issued for an unlimited period [14, part 12 of Art. 13], at the same time the Ministry of Health is empowered to cancel the license [14, part 2 of Art. 16]. The reasons for license cancellation are the following:

- submission of the relevant application by the licensee;
- acceptance by the licensing body of its own decision;
- termination of a legal entity, death of an individual entrepreneur (in case of absence of the legal successor);
- failure to comply with the resolution on elimination of violations of licensing conditions, repeated (within 2 years) violation by the licensee of licensing conditions;
- detection of unreliable data in documents;
- no access for authorized officials of the Ministry of Health to provide an inspection or refusal of it;
- confirmation of the fact of control (decisive influence) on the activity of the licensee by the persons who are residents of the states carrying out armed aggression against Ukraine;
- non-payment for the license.

According to [14, Part 10 of Art. 13], in case of taking a decision on issuing a license and notifying the applicant, the Ministry of Health shall specify the bank details to pay for a license, the payment shall be made by a single transfer in the amount of one minimum wage. Re-issuing of the license is free of charge.

Note, that on November 6, 2017, the Law of Ukraine [6] was introduced granting to the network of state and municipal health care establishments more autonomy in the conduct of medical practice and reforming their organizational and legal status and financing.

In our opinion, an important aspect of state regulation of economic activity in the sphere of medical practice is its motivational component. Thus, an official of a business entity that carries out economic activities in the sphere of medical practice without a license or in violation of licensing conditions is liable [14, art. 20] according to the Code of Ukraine on Administrative Offences [1, art. 164].

It should be noted that the criminal liability for conducting business without license or violation of license requirements has been cancelled [5], but [3] the criminal liability is provided for a similar form of crime related to medical practice. In particular, engaging in medical activities without a special permit by a person who does not have proper medical education, if it has caused grave consequences for the patient, is punishable by correctional labor for a term up to two years, or imprisonment for a term up to three years, or imprisonment for the term up to three years [3, art. 138]. Given the licensing requirements for personnel, we believe that Art. 134, 138 [3] concern the violation of licensing requirements for the conduct of economic activities in the sphere of medical practice.

Conclusions. Consequently, according to the results of the study, it was found that the legislation in the field of regulation of economic activity in the sphere of medical practice is complex, consisting of the rules of various branches of law, which at the same time are related to the same subject of legal regulation. It shows the role of licensing as a main instrument of medical practice activity regulation – the kind of economic activity in the sphere of health care that is provided by the entities exclusively on the basis of a license obtained according to the law and implies the provision of medical care and medical services aimed on the realization of human rights regarding the protection of their health as the highest social value. It is revealed that the process of licensing of economic activity in the modern health care system of Ukraine has sufficient regulatory and legal support. At the same time, it should be noted that modern licensing conditions have significantly simplified the implementation of medical practices in Ukraine, primarily, for individual entrepreneurs. At present, the contradictory provisions of the previous regulations have been eliminated, formal requirements for the information on the material and technical base have been simplified, the regulation of labor relations with the personnel and other personnel aspects have been improved. In the future, further investigation in this area should concern the analysis of the practical application of regulations in the process of licensing of economic activity in the health care system of Ukraine.

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ЛІЦЕНЗУВАННЯ ГОСПОДАРСЬКОЇ ДІЯЛЬНОСТІ У СИСТЕМІ ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ

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У статті обґрунтовано комплексний характер законодавства у сфері регулювання господарської діяльності з медичної практики, яке включає норми різних галузей права, водночас пов'язаних з одним предметом правового регулювання. З'ясовано роль ліцензування як головного інструмента регулювання господарської діяльності з медичної практики – виду господарської діяльності у сфері охорони здоров'я, яка проводиться суб'єктами господарювання виключно на підставі отриманої в установленому законом порядку ліцензії і полягає у наданні медичної допомоги та здійсненні медичного обслуговування, спрямованих на реалізацію прав людини з охорони її здоров'я як найвищої соціальної цінності. Наведено результати аналізу нормативно-правового забезпечення процесу ліцензування господарської діяльності у сучасній системі охорони здоров'я України.

Ключові слова: господарська діяльність; система охорони здоров'я; ліцензування.

ЛИЦЕНЗИРОВАНИЕ ХОЗЯЙСТВЕННОЙ ДЕЯТЕЛЬНОСТИ В СИСТЕМЕ ЗДРАВООХРАНЕНИЯ УКРАИНЫ

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В статье обосновано комплексный характер законодательства в сфере регулирования хозяйственной деятельности по медицинской практике, которое включает нормы различных отраслей права, одновременно связанных с одним предметом правового регулирования. Раскрыта роль лицензирования как главного инструмента регулирования хозяйственной деятельности по медицинской практике – вида хозяйственной деятельности в сфере здравоохранения, которая осуществляется субъектами хозяйствования исключительно на основании полученной в установленном законом порядке лицензии и заключается в предоставлении медицинской помощи и медицинского обслуживания, направленных на реализацию прав человека по охране его здоровья как высшей социальной ценности. Приведены результаты анализа нормативно-правового обеспечения процесса лицензирования хозяйственной деятельности в современной системе здравоохранения Украины.

Ключевые слова: хозяйственная деятельность; система здравоохранения; лицензирование.