Aspects of legal regulation of the provision of medical services

ДЕЯКІ АСПЕКТИ ПРАВОВОГО РЕГУЛЮВАННЯ НАДАННЯ МЕДИЧНИХ ПОСЛУГ

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Abstract

The article focuses on the need to respect human rights in the provision of medical services in Ukraine. It is strictly unacceptable to restrict citizens of Ukraine in receiving free medical services, since such a right is provided for by Art. 49 of the Constitution of Ukraine. It is proposed to consider that a medical service includes all types of medical care and is a special activity in relation to human health. The concept and main signs of medical services are revealed, it is established that the state, local governments, legal entities and individuals, including the patient, can be the customer of medical services. Ukrainian legislation governing the provision of medical services does not meet international standards. The positive experience of the EU countries (France, Denmark, Slovakia) and the world (Australia, Canada) shows that access to medical services is provided within the framework of medical insurance, in most cases free of charge, and is controlled by authorized state organizations.

The purpose of the article is to determine the content, signs of medical services, classification criteria for their subjects, disclose the features of

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Announcement

У статті акцентовано увагу на необхідності дотримання прав людини при наданні медичних послуг в Україні. Категорично неприпустимо обмежувати громадян України в отриманні безкоштовних медичних послуг, оскільки таке право передбачено ст. 49 Конституції України. Запропоновано вважати, що медична послуга включає всі види медичної допомоги і є спеціальною діяльністю щодо здоров'я людей. Розкрито поняття та основні ознаки медичних послуг, з'ясовано, що замовником медичних послуг може бути держава, відповідні органи місцевого самоврядування, юридичні та фізичні особи, включаючи пацієнта. Законодавство України, що регламентує надання медичних послуг, не відповідає міжнародним стандартам. Позитивний досвід країн ЄС (Франція, Данія, Словаччина) та світу (Австралія, Канада) показує, що доступ до медичних послуг здійснюється в рамках медичного страхування, в більшості випадків безкоштовно, та контролюється уповноваженими державними органами.
their legal regulation, clarify the problems of legalization of medical services and improve legislation taking into account foreign experience. The research methodology is based on a systematic approach, which is determined by the specifics of the topic of the article, and is also associated with the use of general and special research methods. The comparative legal method and the method of legal analysis were used in the study of legislative rules governing the provision of medical services. Using the method of legal analysis, groups of subjects of medical legal relations in the field of medical services are determined and their powers are analyzed. The formal logical method was used to differentiate the criteria for distinguishing between the legal structures “medical care” and “medical service”. The results of the study contributed to the identification of certain legal problems that arise when citizens receive medical services and require immediate resolution. It is also advisable to introduce compulsory state health insurance.

Keywords: health care, health insurance, health service, human rights, problems of right implementation.

Introduction

Medical services, their quality, availability, timeliness and sufficiency are one of the factors for the normal functioning of the general health care system. The experience of the leading countries of the European Union shows that the developed market of medical services provides the population with appropriate access to high-quality medical care, indirectly affecting the increase in life expectancy, improving health, preserving the nation’s gene pool.

Life expectancy in Ukraine is 11 years less than in EU countries. In Ukraine, she is 71 years (women - 76, men - 66). And despite the fact this figure was the best compared with 1990 (69 years), however, in the life expectancy rating, Ukraine ranks 111 in the world (World Health Organization, 2015). As of January 2019, the population of Ukraine according to the State Statistics Service is 42101.7 thousand individuals (State Statistics Service of Ukraine, 2019), for 2018 - 42386.4 thousand of which 29315.2 are urban residents and (69.2%) and 13121.3 rural population (30.8%). The population in Ukraine in 2018 compared with 2013 decreased by 818 thousand people, and in 2017 by - 137.1 thousand individuals (Melnik P.S. et.al, 2018). According to the results of measuring of the health index conducted by international and domestic public organizations: in 2016 it was 56 of the maximum 100 points (Health index. Ukraine, 2018). According to experts, about 70% of the polled citizens of Ukraine are not satisfied with the quality of medical services provided in domestic state and municipal medical institutions (Markina A. M., 2018). The impact of medical services on the population of Ukraine, citizens’ dissatisfaction with their provision in state and municipal medical institutions, the difficulty of the implementation of the new medical reform into law enforcement and implementing the legal provisions, the inconsistency of many legal acts in this area determine the relevance of this study.

Ключові слова: медична послуга, медичне страхування, охорона здоров'я, права людини, проблеми правореалізації.
Theoretical framework

In this study, we consider certain aspects of the legal regulation of medical services in the development of the concept of “health and human rights”. The right to health, including access to basic health care, has been recognized as a universal human right in several international agreements (Kingston, L.N., Cohen, E.F. & Morley, C.P. 2010). Dujardin B. (1994) indicates that health and human rights issues must be considered from different perspectives in developed and developing countries. Priority in developing countries continues to be given primarily to improving the quality and effectiveness of medical services and making them accessible to the largest number of people. Castleberry C (2015) notes that the human right to health must be exercised, regardless of racial or ethnic bias, socioeconomic status or geographical location, gender or sexual orientation, age, mental or physical health. In most states, the human right to health is being realized, but cases of violation of this right among the most vulnerable segments of the population remain. Thus, the need to further study the problems of people's access to health services is an urgent issue in the concept of “health and human rights”.

Methodology

The research methodology is based on a systematic approach, which is determined by the specifics of the topic of the article, as well as associated with the using of general and specific research methods. The comparative method and the method of legal analysis were used in the study of the legal rules governing the provision of medical services. Using the method of legal analysis, groups of subjects of medical legal relations in the field of medical services were identified and their powers were analyzed. The formal-logical method was used to differentiate the criteria for the distinction of legal constructs “medical care” and “medical service”, and to establish their concept.

Results and discussion

In international regulatory acts, the term “medical care” and “medical service” both are used. Thus, the International Covenant on Economic, Social and Cultural Rights of 1966 tells of the human right to health and medical care (art.12), of anti-epidemics measures. the WHO Committee may take part in organizing medical assistance to victims of national disasters as it is stated in the Constitution (Constitution) of the World Health Organization. The term “medical service” is used: in the European Social Charter of 1996 on ensuring the effective implementation of the right of migrant workers and their families to protection and assistance in the form of the provision of necessary sanitary and medical services) (Art. 19); in the Charter of Social Rights and Guarantees of Citizens of Independent States of 1994, according to which all individuals employed in the event of illness, regardless of its cause, should be able to use therapeutic and preventive medical services, as well as receive benefits in the case of disability due to illness (injuries), for pregnancy and childbirth, as well as in other cases indicated for by national legislation (Art. 34).

It should also be noted that the term “medical service” was introduced for the first time in the national legislation in 2017. The Law of Ukraine "Fundamentals of the legislation of Ukraine on health care" defines two concepts "medical service" as well as "medical care". Thus, medical care is the activity of professionally trained medical personnel aimed at prevention, diagnosis, treatment and rehabilitation in connection with diseases, injuries, poisonings and pathological conditions, as well as in connection with pregnancy and childbirth (Article 3), and the term “medical service” is the service that is provided to a patient by a healthcare institution or an individual entrepreneur (registered and received a license in accordance with the procedure established by law), and is paid for by its customer. The customer of the medical service may be the State, the relevant local authorities, legal entities and individuals, including the patient (art. 3).

legislation regarding the implementation of the medical package benefits and compulsory insurance. Herbert E.G.M. Herman (1997) studied the right of patients to receive medical care in the Member States of the European Union and proposed to divide these rights into individual and social. André den Exter (2017) also divided the rights of people to individual and social, but noted that they are interdependent and indivisible. Other investigators also addressed problematic issues of access to medical services. For example, Juškevičius, J, Balsienė, J (2010) pointed out the conditions for the lack of financial resources for the effective implementation of guarantees of the right to health in the EU. Hagger L E (2004) studied the court approach to the problem of patients with the right to treatment. Kingston, L.N., et. al. (2010) note the existence in the world of millions of so-called stateless persons who are virtually denied medical care in their countries of residence. Nissen, A. (2018) points to the existence in the Council of Europe member states of the right to access to emergency medical care, a right recognized by the European Court of Human Rights. Thus, a study of the realization of the human right to access to health services has revealed a number of significant problems, such as: global inequalities in health in the world, human rights violations during medical research and clinical trials, lack of financial resources for the effective implementation of human rights guarantees in the field of healthcare, etc.

In the legal literature there is no common interpretation of the terms "medical care" nor "medical service". Some scientists make no distinction between "medical care" and "medical care", considering them to be equivalent (Rusnak L.M., 2016), or indicate that these are different concepts (Vitkova V.S., 2017) or as generalizing the two categories (Antonov S.V.,2006), others consider that “medical service” is part of medical care (Rozhko V.E., 2011). (Pesennikova E.V., Gridnev O.V., Kuchits S.S., 2017), or includes all types of medical care ((Markina A. M. 2018; Polyanskaya E. V., 2010), this point of view will be taken into account. In the scientific literature, the term “medical service” is understood as a combination of various actions of authorized subjects in the provision of tangible or intangible benefits associated with the improvement of the physical and mental health of the population (various types of medical care), both to a single recipient and to an unlimited circle of consumers to ensure their beneficial effect, giving rise to the emergence of appropriate relations in the field of health (Markina A. M. 2018, p.35).

Hertz A. determines that a medical service is an action, defined by law or an agreement, or a set of actions of a medical institution (doctor) which (who) is a service provider, aimed at diagnosing, treating and preventing of a disease, is an independent distinguished object and having a cost meaning (Hertz A., 2015, p.13). Venediktova I., notes that a medical service can be defined as a useful activity of a service provider, which is aimed at meeting the health needs of an individual and which is non-financial (Venediktova I.2014, p. 45). According our point of view, a medical service is a useful activity of a service provider, which is aimed at meeting the health needs of an individual. This service is aimed at diagnosing, treating or preventing of a disease, rehabilitation, and providing medical care related with pregnancy, childbirth and is subject to licensing and having a cost meaning.

There is no single point in the literature regarding the list of signs of medical services. So, Marova S. F., Vork, S.M. (2017) consider that a medical service, 1) does not exist before the start of providing; 2) is laborious and does not have a clear price until its completion; 3) intangible; 4) is difficult to calculate; 5) personified; 6) intellectually dependent on the provider of the service; 6) the quality of the service is variable even when it is performed by the same doctor; 7) based on the service is subjective and depends on the characteristics of the consumer, etc. Bobrysheva O. notes such signs of medical services as: complexity; difficulty in perceiving; frequency of needs for medical services; uncertainty about its necessity; duration of medical service in time, etc. (Bobrysheva O.,2014). According our point of view, the signs of medical services should include: it can be provided both on a paid and free basis; it is the basis for calculating state guarantees of medical care for the population; complexity; has a specific object and subject; personification, frequency, duration of medical services over time, overpriced requirements for the qualifications of a service provider (licensing of activities), the presence of a preparatory period for the consumption of medical services.

The right to medical services is provided only after obtaining a license for the specified type of services. According to paragraph 15 of Part 1 of Art. 7 of the Law of Ukraine no. 222-VIII of 02 May 2015 "On licensing types of economic activity" medical practice is subject to licensing. This practice is carried out by business entities on the basis of a license, subject to the fulfillment of organizational, personnel and technological
requirements for the material and technical base of the licensee (Resolution, 2016).

The legislation contains a number of requirements for the subjects of health care: the presence of premises that meet the established sanitary norms and rules; availability of devices, equipment, equipment in accordance with the report card of medical devices, medical and diagnostic rooms; staffing of medical and pharmaceutical specialists who have previously passed certification. They also need to have: a Statute of a health care institution or regulations on a health care establishment (depending on the legal form); staff list; regulations on its structural divisions; job descriptions of employees; internal regulations of the health care institution; Patient’s clinical routes designed in accordance with clinical protocols and standards (Resolution, 2016; Law of Ukraine no. 2801-XII of 19 November 1992).

The main difference between a “medical service” and “medical care” is its chargeability, that is, a “medical service” can be defined as a specific item of goods having a certain price. So, in 2017, the list of paid medical services was approved, which determined their three groups. They were divided into three blocks: 1) services provided according to functional powers by state and municipal health care institutions: cosmetic care, except for those that are medically indicated; infertility treatment, including surgical methods, artificial insemination and embryo implantation, and others (there are 36 of them in total); 2) services for the implementation of economic and / or production activities; citizens’ stay at their request in medical institutions with improved service and others (there are 7 of them in total); 3) services provided in accordance with the functional authority of higher medical schools and research institutions – for example, in-depth training of individual subjects with more curricula, studying various areas of alternative medicine (11 in total) (Resolution of the CM of Ukraine No. 1138 of 17 September 1996).

Since January 2018, medical services in Ukraine have been provided under the program of medical guarantees. This program determines the list and scope of medical services where the state guarantees full payment for the provision of which to patients at the expense of the State Budget of Ukraine (Art. 2). Within this program, the state guarantees to citizens the full payment related to the provision of:

1) emergency medical care;
2) primary care;
3) secondary (specialized) medical care;
4) tertiary (highly specialized) medical care;
5) palliative care;
6) medical rehabilitation;
7) medical care for children under 16;

The analysis of the regulations of the Law of Ukraine “On State Financial Guarantees of Medical Care of the Population” points to certain legal problems of its implementation. Article 49 of the Constitution of Ukraine provides that the state creates the conditions for effective and accessible medical care for all citizens. In state and municipal health care facilities medical care is provided free of charge. The Constitution of Ukraine does not provide for the possibility of establishing any exceptions to these provisions, except for restrictions in the conditions of martial law or state of emergency (part 2 of article 64) (Law of Ukraine No 2546/96 of 28 June, 1996).

Equal rights of citizens, democracy and the general availability of medical care and other health services are defined as one of the basic principles of health protection in Ukraine (for example, Article 4 of the Fundamentals of Ukrainian Health Care Law) (Law of Ukraine no. 2801-XII of 19 November 1992). Thus, this mechanism of financing the provision of medical services at the expense of budget funds will not help ensure the preservation and restoration of the health of the population of Ukraine.

The actual problem in Ukraine is the inaccessibility of certain medical services, insufficient funding, low efficiency in the use of existing financial resources, the unsatisfactory level of implementation of the program of state guarantees for the provision of medical services (Lehan, V. N., Slabkii, G. O., Shevchenko M. V., (2009) the incompliance of national medical standards with international requirements (Yarosh N.P., 2012). For example, regarding the availability of medical services, in 2015 in Ukraine, 29.3% of family members, if necessary, could not receive medical services, purchase medicines and medical supplies. Also among households whose members needed but did not receive medical services, 52% could not visit a doctor, 45% did not receive treatment in inpatient facilities. Among those who were hospitalized, 93% provided medication themselves to the hospital, 80% - food, 65% - bed linen. Too high cost was named by respondents as the dominant reason for the inability to visit a doctor (87.8% of
respondents), to implement a medical examination (97.1%), to receive medical procedures (98.4%), in-patient treatment (98.7%) (State Statistics Service of Ukraine, 2019). Besides, problems in the provision of medical services (according to the report of the Commissioner for Human Rights of the Verkhovna Rada of Ukraine in 2018) are an insufficient number of general practitioners-family medicine in health institutions that affects adversely the quality of medical services to the population and the possibility of electing a doctor to sign declarations with them; insufficient funding for free and concessional provision of the population with medicines; availability and quality of medical services are not ensured for the most vulnerable groups of the population, in particular for people with disabilities, people with diabetes, patients with rare (orphan) diseases, people who have undergone organ transplants; inappropriate funding for the Affordable Medicines program at the expense of the state budget (Denisova L. L., et. al, 2019). The aspects of interaction of all subjects and participants of medical services, the implementation of real control over the activities of this system and the quality of medical services, as well as the responsibility of health care providers are also not fundamentally important for this sphere of public relations. In particular, the norms on liability for violation of legislation in this area, which are limited by the regulations according to which “persons guilty of violating the law on state financial guarantees for the provision of medical services and medicines, are liable in accordance with the laws, are fragmentary (Article 13) (Law of Ukraine No. 2168-VIII of 19 October, 2017).

For the whole territory of Ukraine, unified rates of payment for the provision of medical services provided to patients under the program of medical guarantees are established. Payment in accordance to the tariff is guaranteed to all medical service providers accordingly with the agreements on the provision of medical services concluded with them (Law of Ukraine No. 2168-VIII of 19 October, 2017). This agreement is concluded in accordance with the general rules for concluding transactions in accordance with the Civil Code of Ukraine. It is bilateral, consensual, and paid (Law of Ukraine No. 435-IV of 16 January, 2003). The subject of this contract is the execution by the contractor of certain actions to provide medical services for the prevention, diagnosis, treatment, rehabilitation, in connection with pregnancy and childbirth. Decrees of the Cabinet of Ministers of Ukraine approved: the mechanism for the conclusion, amendment and termination of the contract on medical care of the population under the program of medical guarantees (Resolution of the CM of Ukraine No. 410 of 04 April, 2018): the operation of the electronic health system and its components, user registration, entry and exchange of information and documents in the electronic system, as well as the mechanism and determination of the amount of publication of information; methodology and accounting for the actual costs incurred by health care institutions in connection with the provision of medical services (Resolution of the CM of Ukraine No. 1075 of 27 December, 2017).

In health care institutions which are providers of medical services under the program of medical guarantees, the amount of paid medical services not included in this program can not be more than 20 percent of the amount of all services provided. The program of medical guarantees is developed taking into account the provisions of industry standards in the health care area, also in accordance with the procedure established by the Ministry of Health of Ukraine, as agreed with the Ministry of Finance of Ukraine, and approved by the Verkhovna Rada of Ukraine as the part of the law on the State Budget of Ukraine for the relevant year (Law of Ukraine No. 2168-VIII of 19 October, 2017) and also in compliance with medical technology documents on the standardization of medical care (Order of the Ministry of Health of Ukraine No. 751 of 28 September, 2012).

The Law of Ukraine "Fundamentals of the Legislation of Ukraine on Health Protection" determines that the system of standards in the health care area is made up of: 1) state social standards; 2) industry standards (medical standard, clinical protocols and medicinal formularies, logbook) (st.141). Note that in modern conditions the standardization of medical services is carried out by harmonizing the standards of medical care with the international standardization system. Unfortunately, in the field of medical activity today there are not too many regulatory requirements and quality standards for the provision of medical services, and therefore, the treatment of many diseases is not provided for by any rules or instructions.

Considering the diversity of medical activities, the diversity of social relations arising in the provision of medical services, it is necessary to distinguish between such groups of subjects of medical legal relations: entities that provide
medical services; subjects receiving medical services; subjects that contribute to the provision of medical services. Consider the powers of the subjects that contribute to the provision of medical services. Thus, the Verkhovna Rada of Ukraine forms by fixing the constitutional and legislative scope for the presentation of medical services, principles and the establishment of standards and amount of budget financing and states the state health care programs (Article 13). The President of Ukraine ensures the implementation of legislation on the provision of medical services through the system of executive authorities. The Cabinet of Ministers of Ukraine organizes the development and implementation of state targeted programs, creates economic, legal, and organizational mechanisms that stimulate effective activity in the provision of medical services. Ministries, other central executive authorities, within their competence, define uniform, science-based state standards, criteria and requirements that should facilitate the implementation of medical services and the protection of public health (Law of Ukraine no. 2801-XII of 19 November 1992).

The Ministry of Health of Ukraine and its bodies, and other ministries, which subordinate health care institutions, take part in the provision of medical services. Thus, the Ministry of Health of Ukraine monitors compliance with health institutions and their quality, availability, approves clinical protocols and standards, takes control over the compliance with them; criteria and standards of the state accreditation of healthcare institutions; unified qualification requirements for staff engaged in certain types of medical and pharmaceutical activities (p.3) (Resolution of the CM of Ukraine No. 267 of 25 March, 2015). The National Health Service of Ukraine, the State Service of Ukraine on Drugs and Drug Control, the State Expert Center of the Ministry of Health of Ukraine, and others, are important in this area. For example, the National Health Service of Ukraine conducts: monitoring, analyzing and forecasting the needs of the Ukrainian population for medical services; concludes, amends and terminates agreements on medical services for the population and agreements on reimbursement; ensures the functioning of the e-health system; pay according to the tariff for the medical services provided to patients under contracts for medical care of the population under the program of medical guarantees (Resolution of the CM of Ukraine No. 1101 of 27 December, 2017). To ensure transparency and public control over the activities of the National Health Service of Ukraine, a Council of Public Control has been created. It consists of 15 people, and is formed according to the results of the competition, which is conducted by rating online voting and re-elected every two years (Resolution of the CM of Ukraine No. 271 28 of March, 2018).

Local state administrations and local authorities have common authority in the presentation of medical services. Thus, local state administrations are responsible for compliance with the legislation on the organization of the work of medical institutions regarding the provision of medical services (Law of Ukraine No. 586-XIV of 9 April, 1999). Local authorities in Ukraine ensure the organization, accessibility and free of charge of medical care for the population, the provision of preferential categories of the population with medicines (Article 32) (Law of Ukraine No. 280/97-VR of 05 May, 1997).

In order to improve the legal regulation of the provision of medical services in terms of improving their quality in Ukraine, we should focus on the positive experience of the countries of the world and the EU. For example, Australia, Belgium, Canada, and France have similar health systems, since they provide state insurance for basic coverage, and private insurance can be purchased by individuals in addition to state insurance (Dixit, SK, Sambasivan, M., 2018). The affiliation, quality and accessibility of medical services in Australia is controlled by a number of government bodies that have their functions in this field at three levels: federal, state and local. In the USA, due to coverage of the cost of medical services with insurance premiums, all services are provided by medical organizations on a paid basis, and there is practically no general health insurance system (Kalashnikov K.N., Kalachikova O.N., 2014, p.138). In Denmark, conscientious citizens who regularly pay taxes can receive timely medical services at no cost. A wider range of medical services is offered in Norway, where the state pays for the cost of not only medical services, but also medical vouchers (Chomoncik M., 2013, p.142). In Finland, medical services of various levels (public health system, and health insurance system) are divided according to the principle of decentralization between local and district health institutions. Health service planning is a joint duty of health councils, municipal councils, and municipal government. (Strizrep T., 2017).

Medical insurance in foreign countries is carried out as a part of the provision of such or another service. So, today a new Lithuanian health program 2020 is being developed using the
“health in all strategies” approach by the creation and strengthening of partnerships with other associated sectors. (Mežiš V. 2013). In Slovakia, compulsory medical insurance, with the volume (package) of basic medical care and a competitive insurance model with selective contracting and flexible pricing policies was introduced in the healthcare system. Health care, with some exceptions, is provided to insured persons for free as in-kind assistance (paid by the third party). (Strizrep T. 2017). So, the experience of the EU countries (France, Denmark, Slovakia) and the world (Australia, Canada) shows that access to medical services is provided as a part of medical insurance. In most EU countries, medical services for citizens are provided free of charge. The quality and availability of medical services are controlled by government bodies.

**Conclusions**

Medical service is a useful activity of a service provider, which is aimed at meeting the health needs of an individual. This service is aimed at diagnosing, treating or preventing of a disease, rehabilitation, and providing medical care related with pregnancy, childbirth and is subject to licensing and having a cost meaning. The signs of medical services should include: it can be provided both on a paid and free basis; it is the basis for calculating state guarantees of medical care for the population; complexity; has a specific object and subject; personification, frequency, duration of medical services over time, overpriced requirements for the qualifications of a service provider (licensing of activities), the presence of a preparatory period for the consumption of medical services. The study shows that in nowadays, citizens of Ukraine when receiving medical services have a number of problems that need to be resolved: 1) inaccessibility of certain medical services; 2) non-compliance of national medical standards with international requirements; 3) low efficiency of using available financial resources; 4) the mechanism for financing medical services in the framework of the medical guarantee program is not fully implemented, which does not contribute to the preservation and restoration of public health; 5) insufficient funding for free and preferential provision of medicines to the population; 6) the availability and quality of medical services for the most vulnerable groups of the population are not ensured.

In order to improve the legal regulation of the provision of medical services, it is necessary to develop a general instruction for the interaction of all entities and participants in this area, to ensure real control over the quality of the provision of such services. An important point in the implementation of medical services is the introduction of mandatory state medical insurance, and the determination of the legal mechanism for the legal liability of health care providers.

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