

PROBLEMS OF LICENSING OF PRIVATE HEALTHCARE FACILITIES IN UKRAINE

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Annotation. The article examines the problems faced by the private sector in obtaining licences to conduct medical practice. The author focuses on both private healthcare facilities and individual entrepreneurs engaged in medical practice.

The author notes that the public healthcare sector alone is not capable to fully satisfy the population's demand for affordable and high-quality medical services, and therefore the growth of the number of private healthcare facilities is inevitable. Analysing the data of the Licensing Register of the Ministry of Health of Ukraine for medical practice, the author notes that more than 60 per cent of all licences were issued to the private sector, but the lion's share of them (85 per cent) were issued to individual entrepreneurs.

The author shares the opinion that only private healthcare facilities are subject to real state regulation in the form of licensing and control with the possibility of administrative and economic sanctions, including cancellation of licences.

The author, in particular, draws attention to the contradictory requirements of the Licensing Conditions regarding staffing of license applicants, who, on the one hand, must submit information on the available staff to obtain a licence, and, on the other hand, must conclude contracts with these employees within a month after obtaining a licence.

The author has studied the circumstances of some court cases where the plaintiffs challenged the decisions of the Ministry of Health of Ukraine to revoke the licence. In the analysed cases, the court satisfied the plaintiffs' claims and found the cancellation of licences to be groundless.

The author also draws attention to the need to regulate the activities of so-called hospital funds, which are correlated with the activities of healthcare facilities but are not subject to licensing.

The author comes to the conclusion that licensing plays a very important role in the establishment and operation of a private healthcare facility, but the current system has numerous inaccuracies and inconsistencies with the practical state of affairs and creates significant pressure on private facilities, which may lead to negative trends in the development of the private healthcare market.

Key words: healthcare facility, hospital funds, licensing, Licensing Register of the Ministry of Health of Ukraine for Medical Practice, medical practice, medical services, private healthcare facility.

1. Introduction.

In recent years, private healthcare has been gaining in importance in Ukraine's healthcare system. The main reasons for this are the dissatisfaction of the population with the quality of services provided by state and municipal healthcare facilities, underfunding of this sector from the state budget, lack of proper communication between the doctor and the patient, etc.

In all civilised countries, the goal of the healthcare system is to ensure that all citizens have access to the necessary quality and affordable healthcare services. The public healthcare sector alone is not able to fully meet this need, so it is inevitable that the private healthcare sector is growing. It is mostly represented by private doctors' offices, various dental and ophthalmological clinics. However, the number of private

clinics offering a wide range of medical services in Ukraine is still small. Thus, according to the Licence Register of the Ministry of Health of Ukraine for Medical Practice, 66,885 licences were issued between 14 February 2001 and 11 October 2023. Of these, 40,380 licences were issued to organisations and facilities of private ownership, 1,863 licences to facilities of state and national ownership, 7,150 licences to facilities of collective ownership, and 11,078 to municipal facilities. Among the organisations and facilities of private ownership that received a licence there were 34,360 individual entrepreneurs, 1,252 limited liability companies, and 71 joint stock companies [1].

Moreover, in large cities, there is competition in the market of medical services among private clinics, which requires the active use of an economic management system adapted to healthcare as an object of economic regulation. The driving force behind the development of private healthcare facilities is demand, which varies depending on the development of economic relations and the growth in the population's income. Under such conditions, competition develops, which contributes to the improvement of the quality of services and has a positive impact on pricing, provided that the relevant market relations are properly regulated by the state. In addition, this market is significantly affected by the conditions of martial law and Ukraine's obligations as a candidate for accession to the EU.

In this respect, state regulation of the healthcare sector is carried out, in particular, through the adoption of regulatory acts, registration of a business entity, licensing and patenting, certification and standardisation, issuance of business permits and the exercise of control and supervisory functions with the possibility of administrative and economic sanctions.

When speaking about the private healthcare sector, the legislator distinguishes two groups of healthcare providers: healthcare facilities – legal entities of any form of ownership and organisational and legal form or their separate subdivisions that provide healthcare services to the population, and individual entrepreneurs who are registered and licensed in accordance with the procedure established by law. In this article, the authors explore the problems of licensing of both groups of the private sector. For example, primary health care is provided free of charge in healthcare facilities and by individual entrepreneurs who have obtained a licence in accordance with the procedure established by law and with whom the main administrator of budget funds has concluded an agreement on medical care for the population (part five of Article 35-1) [2].

At the same time, the insufficiently studied problems of licensing the activities of private healthcare facilities indicate the need for new scientific research in this area.

2. Analysis of scientific publications.

The subject of our study has already been considered, in particular, in terms of improving the mechanisms of public administration, fair distribution of resources between the centre and regions, and ensuring the economic development of the non-productive sphere in the context of market transformations in the country. The key studies are those of the following authors: S. Antoniuk, O. Bayeva, Y. Berezna, O. Bobrysheva, S. Bratus, M. Braginsky, O. Vinnyk, Z. Gladun, V. Dolot, O. Yevtushenko, Y. Ivanov, V. Mamutov, V. Pashkov, Y. Radysh, M. Shutov, V. Shcherbyna, Y. Yanchak, and others.

Theoretical issues related to the provision of administrative services in the field of medical practice licensing have been studied by such researchers as: Z. Zahyney, S. Hromova-Stasiuk, V. Klynchuk, Y. Pavliuchenko, O. Rudenko, V. Stetsenko, N. Saniakhmetova, I. Syniuta, T. Tytovska and others.

At the same time, the problems raised in the studies do not reveal the provisions of the administrative and legal regulation of relations in the health care sector, which is an urgent need of the present.

3. The aim of the work.

The aim of this study is to analyse the problems of licensing of the activities of private healthcare facilities and individual entrepreneurs that arise in the course of providing administrative services.

4. Review and discussion.

Private healthcare facilities occupy a growing share of the healthcare market in Ukraine and play an increasingly important role in meeting the needs of citizens for affordable and quality healthcare services.

Pursuant to Article 16 of the Fundamentals of the Legislation of Ukraine on Healthcare, healthcare facilities in Ukraine may operate on the basis of state, municipal, and private forms of ownership. Private healthcare facilities may choose any organisational and legal form at their discretion. Economic activity in this field shall be supported by the state, but is allowed only with a licence [2].

As noted by some experts in public administration, the private healthcare system is a set of healthcare facilities that carry out private medical activities, i.e. provide medical care [3].

According to clause 15 of part one of Article 7 of the Law of Ukraine “On Licensing of Economic Activities Types”, the list of economic activities subject to licensing includes medical practice [4].

According to the Licensing Conditions for Conducting Business Activities in Medical Practice (hereinafter referred to as the Licensing Conditions), approved by the Resolution of the Cabinet of Ministers of Ukraine No. 285 of 2 March 2016, business activities in medical practice (hereinafter referred to as the medical practice) are a type of business activities in the healthcare sector carried out by healthcare facilities and individual entrepreneurs in order to provide medical care and medical services on the basis of a licence [5].

According to A. Barzylovych, if we consider the market of medical services as a certain system of interaction of socio-political institutions, it should be noted that the entities engaged in activities related to the provision of medical services and subject to the regulatory influence of the state, operate in a system of relations between the institute of public medicine, institute of private entrepreneurial activity aimed at the provision of medical services, a social and public institution that represents the population as a consumer of medical services, expressing requirements and needs for maintaining health, and a separate regulatory institution, a system of norms and rules for regulating the activities of market participants, the functions of which are currently performed by the departments of the Ministry of Health of Ukraine, as well as the functioning of the intermediary institute of insurance medicine. The general national health care system is also an institution, but on a larger scale, in which the relations between all these institutions intersect [6, p. 87].

Ukraine is currently in the process of the transformation of its healthcare system, in which the National Health Service of Ukraine (hereinafter referred to as the NHSU) performs the function of state insurance by providing the population with a guaranteed package of medical services within a set tariff. After entering into an agreement with the NHSU, a healthcare facility receives money under the new funding model.

In accordance with Article 8 of the Law of Ukraine “On State Financial Guarantees of Medical Care for the Population”, a contract for medical care under the medical guarantees programme is concluded between a healthcare facility regardless of its form of ownership or an individual entrepreneur who has obtained a licence to carry out medical practice in accordance with the procedure established by law, and the NHSU. A contract for medical care is a contract in favour of third parties, under which a patient exercises his or her right to choose a doctor by submitting a declaration to the healthcare provider on the choice of a primary care physician. Under the medical guarantees programme the provision of medical services relating to secondary (specialised), tertiary (highly specialised), palliative care and medical rehabilitation is carried out on the basis of a referral from a primary care physician or attending physician in accordance with the procedure laid down by law, unless a referral is not required by law [7].

The Licensing Conditions apply to all legal entities regardless of their organisational and legal form as well as individual entrepreneurs engaged in business activities in medical practice [5], i.e. any form of ownership and organisational and legal form.

First of all, it should be noted that medical practice is carried out according to medical specialties and specialties of junior specialists with medical education, the list of which is approved by the Ministry of Health; by types of medical care (emergency, primary, specialised, palliative, medical rehabilitation); by place(s) of its provision, which is (are) specified in the application for a licence and in the documents attached to it (taking into account the changes made to them submitted by the licensee to the licensing authority) (clause 9). Clause 12 provides a clear list of documentary requirements specifically for healthcare facilities. In the case of surgical interventions (planned and emergency) that require inpatient care, the licensee must perform them on the material and technical basis of healthcare facilities (clause 14) [5]. In other words, a surgeon who is an individual entrepreneur cannot obtain a licence and provide specialised medical care in an inpatient setting, but only in an outpatient setting. In addition, a licensed person is responsible for carrying out such medical actions.

It is also worth mentioning the peculiarities of licensing the medical practice of individual entrepreneurs. Thus, an individual entrepreneur has the right to employ doctors in accordance with the declared specialisation, and junior specialists with medical education depending on the profile (specialisation) provided that their level of qualification meets the uniform personnel requirements approved by the Ministry of Health. The Licensing Conditions allow an individual entrepreneur who does not have special education and does not meet the unified qualification requirements approved by the Ministry of Health to obtain a licence (clause 35). At the same time, they must employ persons with such education (clause 34). An individual entrepreneur is obliged to have a full staff of medical and non-medical workers in accordance with the declared specialisations (clause 35) [5].

After obtaining a licence, a private healthcare facility, as a business entity engaged in medical practice, in addition to the above-mentioned regulatory documents, must comply with the requirements of the Laws of Ukraine "On Consumer Protection", "On Licensing Economic Activities", as well as the Resolution of the Cabinet of Ministers of Ukraine No. 765 of 15.07.1997 "On Approval of the Procedure for State Accreditation of a Healthcare Facility" [8], etc.

D. Zadykhailo believes that administrative mechanisms for regulating the activities of healthcare facilities are widely used in the healthcare sector. At the same time, such regulation is often carried out against the interests of independent subjects of law. The actual rules for healthcare facilities are not so much the requirements of legal acts regulating the civil law relations between the founder and the healthcare facility, but rather the current instructions of higher authorities, which often contradict the constituent documents of healthcare facilities. In the context where laws contain a large number of reference norms which are regulated by local legal acts, the objective law is neglected in favour of managerial directives. These problems can also be solved through the development and adoption of direct action laws that minimise the use of bylaws [9].

For example, the provision of clause 6 of the Licensing Conditions, according to which a list of available staff with an indication of their education and qualification level must be annexed to the application for a licence. At the same time, according to clause 33 of the Licensing Conditions, a legal entity establishing a healthcare facility for the first time and an individual entrepreneur are obliged to conclude an agreement with such an employee or provide information about another employee within one month after obtaining a licence [5].

In our opinion, this provision does not make sense, especially when a private healthcare facility is obtaining a licence for the first time. For example, a healthcare facility that is only planning to obtain a licence to carry out medical practice must have full-time employees. In other words, a doctor, as an employee, must be employed in accordance with the labour legislation. A healthcare facility must pay salaries, withhold from the accrued salary and pay personal income tax (PIT) of 18% and military duty (MD) of 1.5% for the employee, as well as pay the Unified Social Contribution to mandatory state social insurance (USC). This places an additional burden on the manager of the healthcare facility as an employer, as the healthcare facility is not yet operational. In this respect, employees are forced to voluntarily refuse to receive their salaries while being employed by the healthcare facility that is obtaining a licence for the period of its obtaining. This indicates that the legislator does not understand the practical side of this issue.

It is worth noting that the legislation does not provide for separate licensing conditions for private, state, and municipal healthcare facilities. The only exception is for individual entrepreneurs as certain procedures have been simplified for them. This is due to the lack of an alternative for this organisational and legal form.

The current healthcare legislation establishes uniform rules for regulating the activities of healthcare facilities of all forms of ownership, but only private healthcare facilities and individual entrepreneurs are subject to real regulation, such as obtaining a licence to conduct business activities in medical practice. A medical practice licence is issued for an unlimited period, but the Ministry of Health can decide to revoke the licence. Thus, according to the Licence Register of the Ministry of Health of Ukraine for Medical Practice, 155 state, 2368 municipal and 1014 private healthcare facilities had their licences revoked between 14 February 2001 and 11 October 2023 [1]. As for state or municipally owned healthcare facilities, their licences are most revoked due to reorganisation or closure, especially in the countryside. We cannot see the detailed circumstances and reasons for the revocation of licences of private healthcare facilities or individual entrepreneurs, but we can draw some conclusions by examining the circumstances through the Unified State Register of Court Decisions when a licensee appeals against the decision of the Ministry of Health.

For example, case No. 120/1667/23: based on Order No. 2139 of 25 November 2022, the licence of the Ministry of Health to carry out medical practice activities of the “Naukovo-Metodychnyi Tsentр Profpatologii” LLC (hereinafter referred to as Company1) was fully revoked on the basis of the act on the licensee’s refusal to be inspected by the licensing authority dated 18 November 2022 No. 17/347/1. Company1 filed a lawsuit against the Ministry of Health to declare Order No. 2139 unlawful and annul it. The court concluded that in the case in question, the Ministry of Health of Ukraine acted beyond its powers and in violation of the requirements of the applicable law. Therefore, the court stated that the order of the Ministry of Health of Ukraine issued on the basis of an unlawful inspection cannot have any legal consequences for the company and is therefore subject to cancellation in the part of revocation of the licence issued to “Naukovo-Metodychnyi Tsentр Profpatologii” LLC. On the basis of the Decision of the Vinnytsia District Administrative Court, the claim of the Company1 was satisfied [10].

Subsequently, the Ministry of Health lodged an appeal and an appeal procedure was initiated, meaning that the decision of the first instance court did not enter into force. As of today, the licence is in the state of “revoked”, which means that the medical facility cannot carry out economic activities in the field of medical practice.

Case No. 460/13489/21: The Ministry of Health of Ukraine issued Order No. 1454 of 15.07.2021, which revoked the licence of the individual entrepreneur1. According to the position of the individual entrepreneur1, the order was issued without complying with the law; the Ministry of Health had no legal grounds for conducting the inspection; the results of the inspection were drawn up with violations. The inspection was triggered by an appeal from a member of the Ukrainian Parliament to the Ministry of Health. The inspection revealed violations of the terms of the licence. The court found that there were no grounds for conducting an unscheduled state control measure against the plaintiff, no grounds for issuing an Order to conduct an inspection, improper documentation of the inspection report, which did not meet the requirements of the law, meant that there were no legal consequences of the actions taken by the supervisory authority to further implement such an Act, issuing an Order to eliminate violations, issuing a second inspection report and issuing the challenged Order No. 1454. The Rivne District Administrative Court decided to declare illegal and cancel the Order of the Ministry of Health of Ukraine No. 1454 of 15 July 2021 [11].

However, obtaining a licence to carry out medical practice does not solve the issue, as the owner of a private healthcare facility, for example, must also obtain a licence to purchase, transport, store and use controlled substances in its activities.

Besides, the legislator’s position on the operation of not-for-profit hospital funds («лікарняні каси» in Ukrainian) is surprising. Such a charitable organisation or public association is established in accordance with the laws of Ukraine “On Charitable Activities and Charitable Organisations” [12], “On Public Associations” [13] and “Fundamentals of the Legislation of Ukraine on Healthcare” [2], the Decree of the President of Ukraine of 08.08.2000 No. 963/2000 “On Additional Measures to Improve Medical Care for

the Population of Ukraine” [14], orders of the Ministry of Health of Ukraine of 11.08.2005 No. 400 “On Interaction of Hospital Funds, State Authorities, Local Self-Government Bodies and Healthcare Facilities” [15] and “On Functioning of Hospital Funds” of 09.07.2003 No. 315 [16], etc. The activities of such not-for-profit hospital funds are often related to the activities of healthcare facilities that are required to obtain a medical practice licence, but these funds do not need to be licensed. Moreover, according to the latest data of the Ministry of Health, there are more than 200 not-for-profit hospital funds in Ukraine.

5. Conclusions.

Licensing plays a very important role in the establishment and operation of a private healthcare facility, as it ensures standards in this field that affect the safety and quality of medical care provided to patients, as well as the creation of safe conditions for the staff. At the same time, we note that there are a number of practical problems that arise in the process of obtaining a licence to practise medicine by a private healthcare facility. The existing system has numerous inaccuracies and inconsistencies with the practical state of affairs, for example, staffing of a healthcare facility, a large number of not-for-profit hospital funds are not taken into account by the legislator.

Each owner of a private healthcare facility is under considerable pressure from the licensing authority (the Ministry of Health), as the licensing procedure is bureaucratized and regulated (the issue of corruption will require special attention of researches). Therefore, despite a certain desire of our state to develop public-private partnerships in the healthcare sector, the lack of an effective mechanism of state regulation, support and cooperation traces negative trends in the development of the private healthcare market, which, in turn, is currently reducing the burden on the public healthcare system, which is particularly important in the context of Russia’s ongoing invasion of Ukraine.

References:

1. Ministerstvo okhorony zdorovia Ukrainy (2023). Litsenziinyi reistr MOZ Ukrainy z medychnoi praktyky [Licence Register of the Ministry of Health of Ukraine for Medical Practice]. Retrieved from <https://moz.gov.ua/licenzijnij-reestr> [in Ukrainian].
2. Zakon Ukrainy “Osnovy zakonodavstva Ukrainy pro okhoronu zdorovia” [Law of Ukraine “Fundamentals of the Legislation of Ukraine on Healthcare”] No. 2801–XII (19 November 1992). Vidomosti Verkhovnoi Rady Ukrainy, 4, 1993. Retrieved from <https://zakon.rada.gov.ua/laws/show/2801-12#Text> [in Ukrainian].
3. Mieziutseva N., Buravlov L., Radysh Ya. (2008). Pravove rehuliuвання pryvatnoho sektora v okhoroni zdorovia Ukrainy: stan i perspektyvy rozvytku [Legal Regulation of the Private Sector in Healthcare in Ukraine: Current Status and Development Prospects]. Medychne pravo Ukrainy: pravovyi status patsientiv v Ukraini ta yoho zakonodavche zabezpechennia: materialy II Vseukrainskoi naukovo-praktychnoi konferentsii 17-18.04.2008. Lviv. Retrieved from http://medicallaw.org.ua/uploads/media/02_179_01.pdf [in Ukrainian].
4. Zakon Ukrainy “Pro litsenzuvannia vydiv hospodarskoi diialnosti” [Law of Ukraine “On Licensing of Economic Activities Types”] No. 222–VIII (2 March 2015). Vidomosti Verkhovnoi Rady Ukrainy, 23, 2015. Retrieved from <https://zakon.rada.gov.ua/laws/show/222-19#Text> [in Ukrainian].
5. Kabinet Ministriv Ukrainy (2016). Pro zatverdzhennia litsenziinykh umov provadzhennia hospodarskoi diialnosti z medychnoi praktyky [On Approval of Licensing Conditions for Conducting Business Activities in Medical Practice], (Order No. 285 of 2 March 2016). Retrieved from <https://zakon.rada.gov.ua/laws/show/285-2016-%D0%BF#Text> [in Ukrainian].
6. Barzylovykh, A., (2020). Mekhanizmy derzhavnogo rehuliuвання nadannia medychnykh posluh v Ukraini [Mechanisms of state regulation of the provision of medical services in Ukraine]. Publichne upravlinnia ta mytne administruvannia, 1(24), 86-90. <https://doi.org/10.32836/2310-9653-2020-1.17>.



7. Zakon Ukrainy "Pro derzhavni finansovi harantii medychnoho obsluhovuvannya naselennia" [Law of Ukraine "On State Financial Guarantees of Medical Care for the Population"] No. 2168-VIII (19 October 2015). Vidomosti Verkhovnoi Rady Ukrainy, 5, 2018. Retrieved from <https://zakon.rada.gov.ua/laws/show/2168-19#Text> [in Ukrainian].
8. Kabinet Ministriv Ukrainy (1997). Pro zatverdzhennia Poriadku derzhavnoi akredytatsii zakladu okhorony zdorovia [On Approval of the Procedure for State Accreditation of a Healthcare Facility], (Order No. 765 of 15 July 1997). Retrieved from <https://zakon.rada.gov.ua/laws/show/765-97-%D0%BF> [in Ukrainian].
9. Zadykhailo, D., (2005). Derzhava ta ekonomichne rynkove seredovyshche: hospodarsko-pravovy aspekt [State and Economic Market Environment: Economic and Legal Aspect]. Visnyk Akademii pravovykh nauk Ukrainy, 3, 149–161.
10. Yedynyi derzhavnyi reistr sudovykh rishen [Unified State Register of Court Decisions]. Case No. 120/1667/23. Retrieved from <https://reyestr.court.gov.ua/Review/111279191> [in Ukrainian].
11. Yedynyi derzhavnyi reistr sudovykh rishen [Unified State Register of Court Decisions]. Case No. 460/13489/21. Retrieved from <https://reyestr.court.gov.ua/Review/103353110> [in Ukrainian].
12. Zakon Ukrainy "Pro blahodiinu diialnist ta blahodiini orhanizatsii" [Law of Ukraine "On Charitable Activities and Charitable Organisations"] No. 5073-VI (5 July 2012). Vidomosti Verkhovnoi Rady Ukrainy, 25, 2013. Retrieved from <https://zakon.rada.gov.ua/laws/show/5073-17#Text> [in Ukrainian].
13. Zakon Ukrainy "Pro hromadski obiednannia" [Law of Ukraine "On Public Associations"] No. 4572-VI (22 March 2023). Vidomosti Verkhovnoi Rady Ukrainy, 1, 2013. Retrieved from <https://zakon.rada.gov.ua/laws/show/4572-17#Text> [in Ukrainian].
14. Ukaz Prezydenta Ukrainy "Pro dodatkovi zakhody shchodo polipshennia medychnoi dopomohy naselenniu Ukrainy" [Decree of the President of Ukraine "On Additional Measures to Improve Medical Care for the Population of Ukraine"], No. 963/2000 (8 August 2000). Retrieved from <https://zakon.rada.gov.ua/laws/show/963/2000#Text> [in Ukrainian].
15. Ministerstvo okhorony zdorovia Ukrainy. (2005). Pro vzaiemodiiu likarnianykh kas, orhaniv derzhavnoi vlady, orhaniv mistsevoho samovriaduvannia ta zakladiv okhorony zdorovia [On Interaction of Hospital Funds, State Authorities, Local Self-Government Bodies and Healthcare Facilities]. (Order No. 400 of 11 August 2005). Retrieved from <https://mozdocs.kiev.ua/view.php?id=4327> [in Ukrainian].
16. Ministerstvo okhorony zdorovia Ukrainy. (2003). Pro funktsionuvannia likarnianykh kas [On Functioning of Hospital Funds]. (Order No. 315 of 9 July 2003). Retrieved from <https://zakon.rada.gov.ua/rada/show/v0315282-03#Text> [in Ukrainian].

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