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НОВІТНІ ЦИВІЛІСТИЧНІ ІНСТРУМЕНТИ МЕДИЧНОЇ РЕФОРМИ: ПРОБЛЕМНІ ПИТАННЯ ПРАВОРЕАЛІЗАЦІЇ ТА ПРАВОЗАСТОСУВАННЯ

Анотація. *Дослідження новітніх цивілістичних інструментів медичної реформи зумовлене його метою, яка полягає у з'ясуванні правової природи декларації про вибір лікаря, який надає первинну медичну допомогу та договору про медичне обслуговування населення за програмою медичних гарантій, висвітленні особливостей реалізації права на вибір лікаря, зумовлених окресленим інструментарієм, а також виявленні лакун і контроверзій у законодавстві України, судовій практиці при правозастосуванні в цій царині. Основним методом при науковому пошуку став метод вивчення судової практики, що уможливив оцінку ефективності правозастосування, рівня сприйняття законодавства в цій царині на практиці, а також визначення необхідності удосконалення правового регулювання. Висвітлено проблемні аспекти пов'язані з реалізацією права на вільний вибір лікаря, зокрема зумовлених законодавчими змінами щодо медичної реформи. Розкрито правову суть декларації про вибір лікаря, який надає первинну медичну допомогу, з'ясовано, що вона не є правочином, а документом, який засвідчує реалізацію права на вільний вибір лікаря первинної ланки. Проаналізовано договір про медичне обслуговування населення за програмою медичних гарантій та встановлено його цивільно-правову матерію. Визначено, що він є договором про надання послуг за державним замовленням, що укладається на користь третіх осіб. Також досліджено договір про реімбурсацію, що також є договором на користь третіх осіб – пацієнтів у частині повної або часткової оплати відпущених їм лікарських засобів. Проаналізовано судову практику, що дає підстави стверджувати про проблеми з правореалізацією і правозастосуванням, та зроблено пропозиції до удосконалення чинного законодавства, в тому числі в аспекті предмета договору за програмою медичних гарантій. «Законне сподівання», що виникає в людини при наявності нормативних гарантій, перебуває під конвенційним захистом, що ілюструється Європейським судом з прав людини у рішеннях, а для зміни парадигми здійснення необхідні трансформації законодавства. Практичне значення цього дослідження полягає в активізації наукової розвідки в цьому напрямі, в удосконаленні правового регулювання цих новельних юридичних конструкцій, оптимізації правореалізації та правозастосування в окресленій цивілістичній площині.*

Ключові слова: декларація, договір про медичне обслуговування, право на медичну допомогу, медичні послуги, пільгове придбання ліків.

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MODERN CIVILISTIC INSTRUMENTS OF MEDICAL REFORM: ISSUES OF LAW IMPLEMENTATION AND LAW ENFORCEMENT

Abstract. *The study of the latest civilistic instruments of medical reform is conditioned by its purpose, which is to clarify the legal nature of the declaration of choice of primary care physician and the contract for medical care under the programme of medical guarantees, highlighting the specific features of the right to choose a doctor, conditioned by the outlined tolls, as well as identifying gaps and controversies in the legislation of Ukraine and judicial practice in law enforcement in this area. The main method of the study was the method of studying judicial practice, which allowed to assess the effectiveness of law enforcement, the level of perception of legislation in this area in practice, as well as to determine the necessity of improving the legal regulation. The study highlights the problematic aspects related to the exercise of the right to free choice of a doctor, in particular due to legislative changes regarding medical reform. The legal essence of the declaration on the choice of a primary care physician has been covered. The study clarifies that it is not a transaction, but a document certifying the exercise of the right to freely choose a primary care physician. The contract on medical care of the population under the programme of medical guarantees is analysed and its civil law matter is established. It is determined that it is a contract for the provision of services under the public procurement, concluded for the benefit of third parties. The reimbursement agreement was also investigated, which is also an agreement in favour of third parties – patients in terms of full or partial payment for their medicines. The judicial practice is analysed, which gives grounds to assert the problems with enforcement and administration of law, and proposals are made to improve the current legislation, including in the aspect of the subject of the contract under the programme of medical guarantees. The "legitimate expectation" that arises in a person in the presence of regulatory guarantees is under conventional protection, as illustrated by the European Court of Human Rights in its decisions, and to change the paradigm of implementation requires a transformation of legislation. The practical significance of this study is to intensify scientific intelligence in this direction, to improve the legal regulation of these innovative legal constructions, to optimise the enforcement and administration of law in the outlined civilistic plane.*

Keywords: declaration, contract on medical care, the right to medical care, medical services, preferential purchase of medicines.

INTRODUCTION

With the adoption of the Law of Ukraine No. 2168-VIII "On State Financial Guarantees of Medical Care" dated 19.10.2017 (hereinafter referred to as the Law No. 2168-VIII), which is considered to have initiated medical reform in Ukraine, the latest tools that affect both the exercise of a constitutional human right to health care, medical aid and medical insurance, which is guaranteed in Article 49 of the Fundamental Law of the state, and the personal intangible right to medical care, enshrined in Article 284 of the Civil Code of Ukraine. The civilistic arsenal has been replenished with such basic tools as a declaration on the choice of a doctor who provides primary care (hereinafter referred

to as "the Declaration") and an contract on medical care for the population under the medical guarantee programme (hereinafter referred to as "the Contract under the medical guarantee programme").

The relevance of these legal constructions for discussion by scholars and practitioners is significant in view of many factors, including: 1) medical reform is being reviewed for constitutionality in the Constitutional Court of Ukraine within the framework of proceedings on the constitutional petition of 59 people's deputies of Ukraine on the compliance (constitutionality) of the Law No. 2168-VIII with Constitution of Ukraine; 2) the scientific search launched in 2018 with regard to innovative documents at the level of thesis work currently remains at the initial stage of the study, because there are no new studies on those issues; 3) the discussion on the Declaration and the Contract under the medical guarantee programme went beyond being purely scientific, is already illustrated in judicial practice, the analysis of which shows both regulatory controversies and theoretical gaps in these issues. Some aspects of this issue were studied by H. Myronova in the monograph "Modernisation of civil legislation in medical care: theoretical principles and practice of implementation" [1], H. Haro and O. Bobak – in a research-to-practice publication [2]. In the monographic study, H. Myronova addresses only the indirect analysis of the content of the Declaration, namely, clarifies the specific features of the status of the patient's trustee, which is indicated in this document. The researcher identifies the problem of uncertainty of the status of a new subject of legal relations and concludes that the patient's trustee acts based on a contract of voluntary representation on the basis of the relevant articles of the Civil Code of Ukraine and international legal standards recognised by Ukraine, which are applicable to the regulation of relations on voluntary representation of a person in the field of decision-making on treatment and medical care [1]. The authors H. Haro and O. Bobak cover the basic algorithms for concluding the Declaration without addressing its legal essence. Foreign publications contain many articles that cover issues of medical care and contractual constructions in this area, including the work of such scientists as: H.V. Kolisnykova [3], R. Iunes [4], N.S. Vasilevskaya [5], V.Yu. Mammadova [6], Yu. Baulin [7], S. Shishido [8], T. Zhang [9], C. Pardo [10], M.Z. Abesalashvili [11], S. Grant [12], E. Freidson [13]. Gaps in the doctrinal basis are already felt in law enforcement, and therefore, the effectiveness of human rights protection raises doubts. This study continues the scientific monologue with the hope of further constructive dialogues that will be capable of developing a proper doctrinal foundation for practice, including judicial.

The purpose of the study is to clarify the legal nature of the Declaration and the Contract under the medical guarantee programme, to highlight the features of the right to choose a doctor due to the latest tools, as well as identify gaps and controversies in Ukrainian law and judicial practice upon the administration of law in this subject area. Achieving the scientific purpose is possible by performing the following tasks: 1) to disclose the exercise of personal non-property right to free choice of a doctor, which has undergone significant transformations due to medical reform and inconsistency of regulations; 2) to establish the legal nature of the Declaration and the problems of legal understanding in the application of legislative provisions, which creates a violation of the patient's rights; 3) to highlight the new contractual constructions in the field of medical

care and to show the legislative dissonances and problems of judicial practice with conventional inclusions through the lens of the decision of the European Court of Human Rights (hereinafter referred to as "the ECHR").

1. MATERIALS AND METHODS

The methodology of this study is determined by its purpose, objectives and is to highlight the development of legal structures of medical reform, identify features of the latest tools to establish their civilistic matter and place in the civilistic arsenal, which was carried out by means of analysis and interpretation of legal provisions and through the lens of legal science. The scientific study used general scientific methods, primarily dialectical, which occupied a prominent place in the study of modern civil tools, serving to clarify the development of these structures, the development of the author's position on the need to improve their civil regulation and proposals to achieve these goals; methods of analysis and synthesis were the key to distinguishing the features of the analysed legal constructions, the development of conclusions; system method – to clarify the place of the Declaration and the Contract under the medical guarantee programme among the civil law categories. In the process of study, special legal methods were used: Aristotelian – to analyse the internal construction of legal provisions; the method of studying legal practice – for the analysis and generalisation of law enforcement practice and the method of interpreting the law – for clarifying the content of the relevant legal provisions. The theoretical basis is practically absent, because scholars have not studied the problems of the outlined innovative tools in practice, have not developed a sufficient scientific foundation that would serve to optimise the enforcement and administration of law and be the basis for prevention of human rights violations in healthcare. For the first time, the Declaration and the Contract under the medical guarantee programme were scrutinised in the monograph [14] of the author of this study, although despite the urgency and demand of time, it failed to enter the scope of scientific dialogue. This study is a logical continuation of the scientific author's search to catalyse the attention of scholars to the issue, as well as to be useful for practitioners who solve complex issues in both medical and legal practices almost every day.

The legal framework of the study comprises the provisions of the Civil Code of Ukraine[1], several other laws of Ukraine, including Law No. 2168-VIII[2], the Law of Ukraine "Fundamentals of the legislation of Ukraine on healthcare" (hereinafter referred to as "the Fundamentals")[3]. The subject of the analysis also included sublegislative regulations that "implement" medical reform in practice, detailing legislative provisions. The Resolution of the Cabinet of Ministers of Ukraine No. 410 "On some issues of agreements on medical care under the programme of medical guarantees" dated

[1] Civil Code of Ukraine. (2003, January). Retrieved from https://zakon.rada.gov.ua/laws/show/435-15#Text

[2] Law of UkraineNo 2168-VIII "On state financial guarantees of medical care". (2017, October). Retrieved from https://zakon.rada.gov.ua/laws/show/2168-19#Text

[3] Law of Ukraine No 2801-XII "Fundamentals of the legislation of Ukraine on health care". (1992, November). Retrieved from https://zakon.rada.gov.ua/laws/show/2801-12#Text

25.04.2018 (hereinafter referred to as "the Resolution No. 410")[1], the Resolution of the Cabinet of Ministers of Ukraine No. 136 "Some issues regarding reimbursement agreements" dated 27.02.2019 (hereinafter referred to as "the Resolution No. 136")[2], the Order of the Ministry of Health of Ukraine No. 503 "On approval of the Procedure for selection of a doctor who provides primary care and the form of declaration on the choice of a doctor who provides primary care" dated 19.03.2018 (hereinafter referred to as "the Order No. 503")[3]. were also thoroughly studied. The empirical basis of the study included the national judicial practice, namely the decisions adopted in civil and administrative proceedings, as well as the legal positions of the ECHR.

2. RESULTS AND DISCUSSION

The study will cover the specific features of exercising the right to free choice of a doctor, which was influenced by Law No. 2168-VIII, introducing, in particular, the Declaration. Part 2 Article 284 of the Civil Code of Ukraine[4] stipulates that an individual who has reached the age of 14 and who has applied for medical care has the right to choose a doctor and choose treatment methods in accordance with the latter's recommendations.

The exercise of the right to free choice of physician is fraught with numerous statutory dissonances. In accordance with paragraph "d" of Article 6, Part 1 Article 38 of the Fundamentals[5], Part 2 Article 284 of the Civil Code of Ukraine, the patient has the right to freely choose a doctor if the latter can offer their services. Paragraph 3 Part 1 Article 6 of the Law No. 2168-VIII[6] enshrines the patient's right to choose a doctor in accordance with the procedure prescribed by law. According to Article 9 of the Law No. 2168-VIII, in case of need for medical services and medicines under the medical guarantee programme, the patient or their legal representative exercises their right to choose a doctor by submitting a Declaration to the medical service provider. The provision of medical services and medicines under the programme of medical guarantees related to secondary, tertiary, palliative care and medical rehabilitation is carried out under the direction of a primary care physician or a physician in accordance with the procedure prescribed by law, except cases when a doctor's referral is not required according to the legislation.

[1] Resolution of the Cabinet of Ministers of Ukraine No 410 “On some issues of agreements on medical care under the program of medical guarantees”. (2018, April 25). Retrieved from https://zakon.rada.gov.ua/laws/show/410-2018-%D0%BF#Text

[2] Resolution of the Cabinet of Ministers of Ukraine No 135 “Some issues of reimbursement of medicines”. (2019, February). Retrieved from https://zakon.rada.gov.ua/laws/show/135-2019-%D0%BF#Text

[3] Order of the Ministry of Health No 503 “On approval of the Procedure for selection of a doctor who provides primary care and the form of declaration on the selection of a doctor who provides primary care”. (2018, March). Retrieved from https://zakon.rada.gov.ua/laws/show/z0347-18#Text

[4] Civil Code of Ukraine. (2003, January). Retrieved from https://zakon.rada.gov.ua/laws/show/435-15#Text

[5] Law of Ukraine No 2801-XII “Fundamentals of the legislation of Ukraine on health care”. (1992, November). Retrieved from https://zakon.rada.gov.ua/laws/show/2801-12#Text

[6] Law of Ukraine No 2168-VIII “On state financial guarantees of medical care”. (2017, October). Retrieved from https://zakon.rada.gov.ua/laws/show/2168-19#Text

Article 35-1 of the Fundamentals establishes the general procedure for choosing a family doctor, the details of which are in the sub-legislative act of the Ministry of Health of Ukraine, namely the Order No. 503[1]. At the secondary and tertiary levels of medical care, there is no free choice of doctor, as it is stated that the attending physician for secondary or tertiary care in a healthcare institution that provides such care is determined by the head of this institution or a person authorised to take the corresponding decisions (Articles 35-2, 35-3 of the Fundamentals). However, Part 2 Article 34 of the Fundamentals guarantees the patient's right to demand a change of doctor.

Provision of medical care to patients at the secondary level is carried out: 1) under the direction of the attending physician for the provision of primary care; 2) at the direction of the attending physician of the healthcare institution that provides secondary (specialised) or tertiary (highly specialised) medical care; 3) without referral is provided to patients who have applied to: a) obstetrician-gynaecologist; b) dentist; c) a paediatrician; d) patients with chronic diseases who are registered at the dispensary in this healthcare institution; e) patients who are in an emergency.

Similarly, Article 35-3 of the Fundamentals establishes the conditions for the level of tertiary care. Tertiary care is provided to patients: 1) at the direction of the attending physician for the provision of primary or secondary (specialised) medical care; 2) at the direction of a healthcare institution that provides primary, secondary (specialised) or tertiary (highly specialised) medical care, including other specialisation; 3) without referral is provided: a) to patients with chronic diseases who are registered at the dispensary in the relevant highly specialised multidisciplinary or single-profile healthcare institution; b) patients who are in an emergency.

Thus, the patient's ability is regulated within one legislative document – the Fundamentals, but there is a regulatory diversity in approaches: on the one hand, the patient can choose any doctor, but, on the other hand – the choice is full of obstacles. Such statutory conflict creates the need to resolve it through the lens of the letter of the Ministry of Justice of Ukraine No. 758-0-2-08-19 "On the practice of applying the law in case of conflict" dated 26.12.2008[2] in favour of a special provision. Finding out which of the provisions is special, the study addresses the fact that Articles 6 and 38 of the Fundamentals concern precisely the rights of the patient, while Articles 35-1 through 35-3 of the Fundamentals concern the procedure for providing medical care of various types. Thus, there is reason to believe that in case of internal conflicts of provisions, those concerning the rights of the patient will be special. Such internal legal disputes should be eliminated by amending the Fundamentals and choosing a single model to regulate the exercise of the right to free choice of physician.

The aggravation of statutory dissonances is conditioned by the adoption of the Order of the Ministry of Health of Ukraine No. 586 "On approval of the Procedure for referring patients to healthcare institutions and individuals-entrepreneurs who have

[1] Order of the Ministry of Health No 503 “On approval of the Procedure for selection of a doctor who provides primary care and the form of declaration on the selection of a doctor who provides primary care”. (2018, March). Retrieved from https://zakon.rada.gov.ua/laws/show/z0347-18#Text

[2] Letter of the Ministry of Justice of Ukraine No 758-0-2-08-19 “On the practice of applying the law in case of conflict”. (2008, December). Retrieved from https://zakon.rada.gov.ua/laws/show/v0758323-08#Text

received a license to conduct business in medical practice and provide medical care" dated 28.02. 2020[1] (hereinafter referred to as "the Order No. 586"). The patient will be provided with medical services in an outpatient or inpatient setting, medical services provided by field teams, laboratory, instrumental or functional studies only through the referral. The initiator of the referral is the primary care physician on the choice of whom the patient has submitted a relevant declaration in accordance with the law, or another attending physician of the patient who decides on the referral. Item 4 Section I of the Order approved by the Order no. 586 expands the specialties of doctors whose care patients can seek without referral when receiving secondary medical care, namely: a) an obstetrician-gynaecologist; b) a psychiatrist; c) a narcologist; d) a dentist; e) a paediatrician; e) a tuberculosis specialist. Wording of Part 9 Article 35-2 of the Fundamentals gives grounds to claim an exclusive list of medical specialties, which should not be detailed in the sub-legislative act, but the legislator has chosen the path of an expansionary approach and the definition of additional specialties. When a patient applies for medical services, the authorised person of the service provider must, in particular, agree with the patient on the choice of a doctor or other medical professional of the business entity who will provide referral services if possible. Therefore, there is another regulatory barrier "if possible", which is an evaluative concept and it is unclear what objective criteria should be followed, keeping in mind the guaranteed personal inalienable right to medical care with full choice, but in a transformational change – with the maximum restriction on the volume of sales.

In summary, the Law No. 2168-VIII is special, because it regulates the procedure for providing medical care at the expense of the State Budget of Ukraine under the programme of medical guarantees. Therefore, the following conclusions can be drawn:

1) when providing medical care under the programme of medical guarantees, the patient's right to freely choose a doctor is limited by the choice of a primary care physician;

2) the choice of a doctor in the provision of other types of medical care under the programme of medical guarantees is subject to numerous regulatory restrictions, which does not allow to fully experience the freedom of choice in the exercise of personal non-property right to medical care;

3) when providing medical care outside the programme, free choice must be provided based on Articles 6 and 38 of the Fundamentals. However, it is clear that this does not correlate with Article 24 of the Constitution of Ukraine[2]: citizens have equal constitutional rights and freedoms and are equal before the law.

Next, the study analyses the tool for exercising the right to free choice of a doctor – the Declaration, which serves as the beginning of exercising the right to medical care, considering it with a projection on judicial practice. The decision of the Melitopol Municipal and District Court of the Zaporizka Oblast dated 18.12.2019 (case No.

[1] Order of the Ministry of Health of Ukraine No 586 “On approval of the Procedure for referring patients to health care institutions and individuals – entrepreneurs who in the manner prescribed by law received a license to conduct business in medical practice and provide medical care of the appropriate type”. (2020, February). Retrieved from https://zakon.rada.gov.ua/laws/show/z0235-20#Text

[2] Constitution of Ukraine. (1996, June). Retrieved from https://zakon.rada.gov.ua/laws/show/254%D0%BA/96-%D0%B2%D1%80#Text

937/9145/19) [15] ruled as follows: to satisfy the claims of PERSON_1 to the Municipal Non-Profit Enterprise "Centre of Primary Health Care of Melitopol District Council of the Zaporizka Oblast", Terpinnia Outpatient Clinic of General Practice of Family Medicine, Municipal Non-Commercial Enterprise "Melitopol Central District Hospital" on the recognition of the actions of the defendants as illegal and its obligation to take certain actions. To recognise the actions of the Municipal Non-Profit Enterprise "Centre of Primary Health Care of Melitopol District Council of Zaporizhia Region", Terpinnia Outpatient Clinic of General Practice of Family Medicine, Municipal Non-Commercial Enterprise "Melitopol Central District Hospital" as illegal, which lie in refusing to provide medical services. To oblige the authorised persons of the Terpinniv Outpatient Clinic of General Practice of Family Medicine to conclude the agreement with PERSON_1 on rendering medical services.

The plaintiff PERSON_1 substantiated his claims by the fact that since 2018, he applied to the local hospital with a proposal to enter into a contract with a therapist four times, but was denied, and he is an elderly man who underwent heart surgery and amputation of his left arm. The therapist PERSON_2 explained that she refused to sign a contract with him not during, but after she and her colleagues entered into contracts with other patients (*author's note – please note that this refers to the Declaration, which is incorrectly interpreted herein as a contract*) when doctors began to deny patients medical care. The plaintiff stated that he could not come to the doctor and receive therapeutic services.

Furthermore, the plaintiff noted that on May 27, 2016 at 1:30 p.m. he came to the district hospital to visit the dentist. However, the dentist refused to see him because the plaintiff had not previously made an appointment with a doctor, although there were no patients in the dentist's office. The plaintiff stated that he did not have a landline phone to make an appointment with a doctor, and it was expensive for him to call from a mobile to a landline phone. By his refusal, the doctor caused material damage to the plaintiff because he had spent money on this trip. As a result, the medical staff of the Central District Hospital once again ignored the right of citizens stipulated in Article 49 of the Constitution of Ukraine.

In court proceeding, the representative of the defendant of Municipal Non-Commercial Enterprise "Melitopol Central District Hospital" objected to the claim, considering it unfounded and groundless. She noted that PERSON_1 applied to the dentist's office on 27.05.2019, but after working hours, at 2:40 p.m. He was informed about the work schedule of the dentist and was recommended to contact the standby dentist at "Melitopol City Dental Clinic" under the Melitopol City Council of the Zaporizka Oblast, or on 28.05.2019 to Municipal Non-Commercial Enterprise "Melitopol Central District Hospital" under the Melitopol District Council for medical care. He was not deprived of the right to medical care. The hospital did not render services to the plaintiff, and the plaintiff was only informed about the work schedule of the dentist and was recommended to contact the standby dentist. The representative of the defendant requested the court to deny the plaintiff in satisfaction of the claims in full.

Representative of the defendant of the Municipal Non-Profit Enterprise "Centre of Primary Health Care of Melitopol District Council of the Zaporizka Oblast", the structural unit of which is Terpinnia Outpatient Clinic of General Practice of Family

Medicine – V. V. Soroka at the hearing against the claim objected, explained that the plaintiff was denied a declaration for primary care, because the doctors available in the clinic have already made the optimal number of declarations. The optimal number of persons with whom doctors of general practice of family medicine can conclude Declarations is 1,800 people per one general practitioner-family doctor, 2,000 people per one doctor-therapist. According to the staff list of Municipal Non-Profit Enterprise "Centre of Primary Health Care of Melitopol District Council of the Zaporizka Oblast" in the outpatient clinic of general practice of family medicine of the Terpinnia Village work three family doctors. At the time of the inspections at the request of the plaintiff, i.e. on 08.05.2019, it was established that all doctors of the Terpinnia Outpatient Clinic of General Practice of Family Medicine have concluded the optimal number of Declarations, in the amount of over 1,800 per doctor and therefore are incapable of concluding a declaration with the plaintiff.

Having comprehensively analysed the circumstances in their entirety, having assessed the evidence gathered in the case, the court, proceeding from its internal conviction, which is based on a full, objective, and comprehensive clarification of the circumstances of the case, considered that the actions of the defendants, which lay in refusing to provide PERSON_1 with therapeutic and dental services are illegal. Furthermore, according to the medical report of Terpinnia Outpatient Clinic of General Practice of Family Medicine dated 30.09.2014, the plaintiff is a person with a disability, can move in the surrounding area near the house where he resides in the Terpinnia Village, and the conclusion of a contract for primary care (*author's note – again, please note that this is a Declaration, which does not constitute a transaction*) with doctors of outpatient clinics of general practice of family medicine in the villages of Semenivka, Astrakhanka, Myrne urban-type settlement, Myrne village, Polianivka village, Novopylypivka village will create inconvenience to the plaintiff and lead to a violation of his rights and freedoms guaranteed by the Constitution of Ukraine (*author's note – and, admittedly, personal non-property right to medical care, prescribed in Article 284 of the Civil Code of Ukraine*).

The court obliged the authorised persons of Terpinnia Outpatient Clinic of General Practice of Family Medicine to enter into a contract with PERSON_1 on the provision of medical services, and satisfied the claims of PERSON_1 as legal and reasonable.

The given decision testifies to numerous problems with the enforcement and administration of law, namely: a) the decision should not be about the contract for the provision of medical services, but the Declaration, which will allow the patient to receive primary care, and if necessary, under the direction of a primary care physician – other types of medical care. It appears that the court incorrectly defined the legal nature of the Declaration by obliging the healthcare institution to enter into a contract; b) incorrectly chosen method of protection of the plaintiff's right. According to Item 5 Section 3 of the Order of a choice of the doctor providing primary medical care, and the form of the declaration on the choice of the doctor providing primary medical care approved by the Order No. 503, primary care providers are prohibited from refusing to accept the Declaration and keep the patient, in particular based on the patient's chronic disease, age, sex, social status, financial status, registered place of residence, etc. However, the patient must take into account that they have the right to choose a doctor who provides primary

care, provided that the number of patients who have already chosen such a doctor in accordance with the Procedure does not exceed the optimal practice (paragraph 2 Section 2 of the Order). Therefore, considering that the patient's application for the Declaration was timely, but was wrongly denied, the court should have ordered the adoption of the Declaration, which would therefore serve to provide medical care to the patient.

In continuation of this case, the decision of the Novokakhovka City Court of the Khersonska Oblast dated 01.06.2020 (case No. 661/557/20) deserves attention [16], which fully satisfied the claims of PERSON_2 to the Municipal Non-Commercial Enterprise "Centre of Primary Healthcare of the City of Nova Kakhovka" under the Novokakhovka City Council regarding the cancellation of the order on disciplinary punishment. The reason for disciplinary action, according to the employer, was a misdemeanour, namely not accepting the patient for admission. The plaintiff stated that this patient was examined by him as a physician on November 13, 2019, as evidenced by the record of her examination, and based on recommendations for discharge from the infectious diseases department and infectious disease specialist of the Infectious Diseases Office, was sent for consultation to a neurologist Central City Hospital of the Nova Kakhovka city. The plaintiff also noted that the patient PERSON_6 concluded the Declaration with another physician who was at work. The parties in the case did not deny the fact that PERSON_6 voluntarily concluded the Declaration with another doctor-therapist and on 13.11.2019, the registry staff, for unknown reasons, registered him for an appointment with a doctor-therapist PERSON_2, who also holds the position of head of the Outpatient Clinic No. 2 under the Hospital.

Notably, in accordance with Item 3 Section 2 of the Procedure approved by Order No. 503, during the period of temporary absence of the doctor chosen by the patient, due to leave or other circumstances that make it temporarily impossible to receive patients by a doctor, the patient has the right to receive medical services from another doctor of the same primary care provider without new Declaration. In view of the circumstances of the case and national law, the court in this case correctly established the absence of a disciplinary offence in the actions of PERSON_2.

Judicial practice gives grounds to dwell once more on the clarity of the legislation and the proper theoretical substantiation of new legal constructions. According to Order No. 503, declaration means a document confirming the will of the patient (their legal representative) to choose a doctor who will provide them with primary care. In the Operational Manual of the Ministry of Health of Ukraine "How to organise the system of primary healthcare at the local level" [17] the Declaration means the statement of the patient (their legal representative), which confirms the patient's will to choose a doctor who will provide primary care. Declaration form approved by Order No. 503 has already undergone regulatory changes and updates, and therefore, its legal essence has changed. Therefore, the Declaration is not legal in nature.

Analysis of Article 202 of the Civil Code of Ukraine, Law No. 2168-VIII and Order No. 503 suggests several conclusions about the legal nature of the Declaration:

1) the change in the regulations of the Declaration affected the change of its legal nature: from a unilateral transaction in the original version (which creates obligations not only for the person who committed it, i.e. an individual, but also for other persons, in particular, for the health care provider, the National Health Service of Ukraine) in the

action of an individual (statement on the will of an individual of the choice of the doctor who provides primary care) in the current wording;

2) the declaration serves the emergence of new legal relations on another basis – the Contract under the medical guarantee programme;

3) it appears that the applicant is indicated incorrectly in the Declaration, namely as a patient. According to Article 3 of the Fundamentals, a patient is an individual who has sought and/or is receiving such care. The declaration does not give rise to legal relations in the field of medical care, an individual who applies to a healthcare provider does not do so for the purpose of receiving medical care, therefore, to mark the applicant as a patient is incorrect. The provision of Part 2 Article 9 of Law No. 2168-VIII is similarly incorrectly worded. An individual will become a patient only if they apply, for example, for primary care to a healthcare provider;

4) the declaration has a double legal meaning:

a) certifies the exercise of the right to freely choose a doctor (although an individual is not yet a patient);

b) is a legal fact that confirms the emergence of a natural person's status as a third party pursuant to the Contract under the medical guarantee programme;

5) the declaration is an element (legal fact) of the legal structure, which gives rise to legal relations in the field of medical care.

Another instrument generated by medical reform, which affects the exercise of personal non-property right to medical care, is the *Contract under the medical guarantee programme*, which is concluded for the benefit of third parties. The concept of this Contract was introduced into the legislative plane by Law No. 2168-VIII and detailed in Resolution No. 410[1]. The parties to the Contract under the medical guarantee programme are the provider of medical services (healthcare institutions and individuals-entrepreneurs engaged in economic activities in medical practice) and the Authorised body (central executive body that implements the national policy in the field of public financial guarantees of medical care – the National Health Service of Ukraine). The Contract under the medical guarantee programme can be concluded either in writing or in electronic form. A patient who requires the provision of medical services or medicines under the medical guarantee programme, or their legal representative, applies to the medical service provider and submits a Declaration.

The analysis of regulations and doctrinal sources suggests the following: a) the Contract under the medical guarantee programme by nature is a contract for the provision of services; b) according to the principle of dichotomy, this contract consists of two parts: 1) in the part "customer – provider", it is a contract for the provision of services under public procurement; 2) in terms of rendering medical services by the provider to the patient, it is a contract for the benefit of third parties. This position, in particular, received regulatory confirmation in Article 8 of the Law 2168-VIII and item 13 of the Standard form of the Agreement on medical service of the population under the medical guarantee programme approved by the Resolution No. 410.

We believe that the Contract under the medical guarantee programme is civil in

[1] Resolution of the Cabinet of Ministers of Ukraine No 410 “On some issues of agreements on medical care under the program of medical guarantees”. (2018, April). Retrieved from https://zakon.rada.gov.ua/laws/show/410-2018-%D0%BF#Text

nature and is described by the following features: a) the parties to the agreement are equal participants in the contractual relations with a statutorily defined scope of rights and obligations; b) the purpose of entering into these contractual relations is to meet the state needs related to medical care, because everyone has a natural inalienable and inviolable right to medical care. The state need is formed based on the programme of the state guarantees of medical service of the population; c) payment for medical services provided under the contract will be made at the expense of the State Budget of Ukraine based on budget legislation, which does not affect the civil nature of the obligations of the parties under the contract (Parts 4-5 Article 18 of the Fundamentals); d) to become a contractor under a healthcare contract, the business entity must comply with regulatory requirements, in particular register in the electronic healthcare system, also register its medical staff, and the customer has no right to refuse to enter into a contract in case of compliance with them and provide relevant medical services (within the medical guarantee programme).

According to Article 8 of Law 2168-VIII, the subject of the agreement on medical care is medical services and medicines under the medical guarantee programme, and in Resolution No. 410 – medical services only. Therefore, the logical question arises: how does the legislator see the practical aspect of purchasing medicines within the medical guarantee programme? It is necessary to introduce changes to the standard form of the contract, because Resolution No. 410 contains a double mention of medicines (subparagraph 6 of paragraph 19, paragraph 24-1 of the Standard form of the Contract under the medical guarantees programme)), and therefore, the broad wording of the subject is problematic considering the nature of the contract.

Article 9 of Law No. 2168-VIII stipulates that in case of need for medical services and medicines under the medical guarantee programme, the patient (their legal representative) applies to the provider of medical services in accordance with the procedure prescribed by law. The procedure for reimbursement of medicinal products under the medical guarantee programme for the relevant year, the standard form of the reimbursement agreement, the procedure for its conclusion, changes and termination shall be approved by the Cabinet of Ministers of Ukraine.

To date, a Standard Form of Reimbursement Agreement has been developed and approved by Resolution No. 136[1], and also the regulations of reimbursement of medicines are defined based on the Resolution of the Cabinet of Ministers of Ukraine No. 135 "Some issues of reimbursement of medicines" dated 27.02.2019[2]. Please note that the reimbursement of medicines is carried out for the outpatient treatment of cardiovascular disease, type II diabetes, and asthma. The subject of the reimbursement agreement is medicines dispensed by pharmacies at retail prices specified in the Register of medicines subject to reimbursement, approved in accordance with the procedure prescribed by law, with reimbursement of the cost of medicines by the National Health Service of Ukraine in full or in part to the pharmacy, The medicines are granted to

[1] Resolution of the Cabinet of Ministers of Ukraine No 136 “Some issues regarding reimbursement agreements”. (2019, February). Retrieved from https://zakon.rada.gov.ua/laws/show/136-2019-%D0%BF#Text

[2] Resolution of the Cabinet of Ministers of Ukraine No 135 “Some issues of reimbursement of medicines”. (2019, February). Retrieved from https://zakon.rada.gov.ua/laws/show/135-2019-%D0%BF#Text

patients based on electronic prescriptions, records of which are entered into the electronic healthcare system. This agreement is also an agreement for the benefit of third parties-patients in terms of full or partial payment for their medicinal products.

Problems that arise in practice through new contractual algorithms are best traced through court case illustrations.

On June 16, 2020, the Eighth Administrative Court of Appeal considered the case [18] on declaring illegal the defendant's inaction on failure to take measures to restore the violated right to preferential purchase of medicines; recognition of the defendant's inaction on failure to take measures to resolve the issue of liability of persons due to whose fault the plaintiff's rights to preferential purchase of medicines were committed; declaring illegal the defendant's inaction on failure to take measures to compensate for material damage caused to the plaintiff as a result of violation of his right to preferential purchase of medicines; the defendant's obligation to take measures to compensate for material damage caused to the plaintiff as a result of violation of his right to preferential purchase of medicines; restoration of the violated right of the plaintiff to preferential purchase of medicines; resolving the issue of liability of persons through whose fault the plaintiff's rights to preferential purchase of medicines were violated; recovery of non-pecuniary damage in the amount of 133,102.50 UAH from the Department of Health of Lutsk City Council in favour of the plaintiff.

According to Part 5 Article 38 of the Law of Ukraine "On the fundamentals of social protection of persons with disabilities in Ukraine"[1] persons with disabilities of the first and second categories, being in outpatient treatment, have the right to purchase drugs on prescription with payment of 50 percent of their cost. The plaintiff is a person with a disability of II category who, on 08.01.2020, based on a prescription for preferential purchase of medicines, applied to the pharmacy No. 65 DVTP "Volynpharmpostach" in order to purchase drugs with a 50 percent discount, however, employees of the pharmacy denied the plaintiff the sale of medicines by prescription for preferential purchase of medicines, as a result of which the plaintiff paid the full cost of medicines in the amount of 173,.80 UAH. The plaintiff therefore considered that he had suffered material damage in the amount of UAH 86.90. On 09.01.2020, the plaintiff sent a complaint to the Health Department of the Lutsk City Council with a request to compensate the damage and provide information about the officials guilty of violating his legal rights. Department of Health of Lutsk City Council by letter No. 17-18/40/2020 dated 27.01.2020 informed the plaintiff that the receipt of medicines on preferential terms is possible after the conclusion of the relevant agreement between the medical institution and the pharmacy. Since such an agreement was concluded on 13.01.2020, after this date the plaintiff had the right to apply for the purchase of medicines on preferential terms. By virtue of the peremptory provision of Article 38 of the Law of Ukraine "On the Fundamentals of Social Protection of Persons with Disabilities in Ukraine", the plaintiff considered the defendant's refusal to ensure the right to preferential purchase of medicines to be unlawful.

The position of the defendant was that in accordance with the Resolution of the Cabinet of Ministers of Ukraine No. 391 "On approval of requirements for the provider

[1] Law of Ukraine No 875-XII “On the basis of social protection of persons with disabilities in Ukraine”. (1991, March). Retrieved from https://zakon.rada.gov.ua/laws/show/875-12#Text

of medical services, with which the main managers of budget funds concluded agreements on medical care" dated 28.03.2018, the Department of Health of the Lutsk City Council enters into agreements on medical care for the population for the budget year with municipal non-profit health care enterprises as recipients of budget funds[1], the Department of Health of the Lutsk City Council enters into agreements on medical care for the population for the budget year with municipal non-profit health care enterprises as recipients of budget funds.

According to the decision of the session of the Lutsk City Council No. 68/3 "On the Budget of the Lutsk City Territorial Community for 2020" dated 24.12.2019 concerning limit certificates of the Department of Finance and Budget of Lutsk City Council for 2020 dated 08.01.2020, the Department of Health of Lutsk City Council provided limit certificates to municipal non-profit healthcare enterprises of Lutsk City Territorial Community and concluded agreements on medical care for the budget year from 09.01.2020 with certain amounts of expenditures directed at the use of budget funds, including for reimbursement of free prescriptions for privileged categories of patients.

According to the requirements of the Budget Code of Ukraine, municipal healthcare enterprises have the right to initiate the procedure of concluding agreements with enterprises and organisations, including pharmacies, in the presence of budget allocations. Therefore, only from the moment of allocation of budgetary funds to the municipal healthcare institution, such has the right to begin the procedure of concluding agreements with pharmacy.

Municipal enterprise "Lutsk Primary Care Centre No. 1", where the plaintiff was on an outpatient treatment, entered into a contract with the pharmacy DVTP "Volynpharmpostach" on 13.01.2020. Therefore, the defendant considered that it had not committed unlawful inaction, as it had taken the necessary steps to ensure that the right of citizens, including the plaintiff, to receive medicines on preferential terms was ensured.

Item 2 of the Resolution of the Cabinet of Ministers of Ukraine No. 1303 "About streamlining of free and preferential release of medicines according to prescriptions of doctors in case of out-patient treatment of separate groups of the population and on certain categories of diseases" dated 17.08.1998 (hereinafter referred to as "the Resolution No. 1303")[2] stipulates that the release of medicines free of charge and on preferential terms in the case of outpatient treatment of persons is carried out by pharmacies on prescriptions issued by doctors of treatment and prevention facilities at the place of residence of these persons. Paragraph 2 of Annex No. 1 to Resolution No. 1303 stipulates that persons with disabilities of I and II category belong to the groups of the population in the case of outpatient treatment of which prescription medicines are dispensed with payment of 50 percent of their cost in accordance with the Law of

[1] Resolution of the Cabinet of Ministers of Ukraine No 391 “On approval of requirements to the provider of medical services, with which the main managers of budget funds enter into agreements on medical services”. (2018, March). Retrieved from https://zakon.rada.gov.ua/laws/show/391-2018-%D0%BF#Text

[2] Resolution of the Cabinet of Ministers of Ukraine No 1303 “On streamlining free and preferential dispensing of medicines on prescription in the case of outpatient treatment of certain groups of the population and for certain categories of diseases”. (1998, August). Retrieved from https://zakon.rada.gov.ua/laws/show/1303-98-%D0%BF#Text

Ukraine "On Fundamentals of Social Protection of Persons with Disabilities in Ukraine".

The Court of Appeal found that the plaintiff is a person with a disability of II category, in accordance with Resolution No. 1303 has the right to release drugs on prescription with payment of 50 percent of their cost. At the same time, the Court of Appeal noted that the dispensing of prescription drugs with payment of both 50 percent of their cost and free of charge takes place in accordance with a particular procedure established by the state.

In particular, the Resolution of the Eighth Administrative Court of Appeal states: medical care is provided free of charge at the expense of budget funds in healthcare facilities and individual entrepreneurs who are registered and licensed to conduct business in medical practice, with which the main budget managers have concluded agreements on medical care for the population. Medical care contracts are concluded within the budget funds provided for healthcare for the relevant budget period, based on the cost and volume of health care services, the customer of which is the state or local governments. The cost of a health care service is calculated based on the cost structure required to provide such a service in accordance with industry standards in the field of healthcare. The Cabinet of Ministers of Ukraine approved the method of calculating the cost of medical services and the list of paid medical service. The procedure for concluding agreements on medical care for the population under the medical guarantee programme and the procedure for determining tariffs for payment for medical services and medicines shall be established by the Law No. 2168-VIII.

Dispensing of prescription drugs with payment of 50 percent of their cost, and free of charge, is carried out depending on the funds provided for this purpose in the state and local budgets. The Law No. 2168-VIII, which regulates the procedure for concluding contracts for medical care under the medical guarantee programme and the procedure for determining tariffs for payment of medical services and medicines, does not make provision for the terms of concluding contracts for medical care.

Thus, the appellate court held that the defendant did not commit unlawful inaction, because it took all necessary steps to ensure the right of citizens, including the plaintiff, to receive drugs on preferential terms. Therefore, the court refused in satisfaction of the claim for inaction of the defendant to ensure the right the plaintiff on preferential purchase of medicines.

This is an example of causing negative consequences for an individual, in particular, being a person with a disability who has the right to dispense prescription medicines with payment of 50 percent of their cost, which was established by the court and clearly guaranteed by the Law of Ukraine "On Fundamentals of Social Protection with Disabilities in Ukraine". Resolution No. 1303 does not make provision for any contractual conditions in the regulation of the granting of preferential provision of medicines. Thus, regulatory obstacles exist precisely because of the vagueness of the provisions of the Law No. 2168-VIII, as noted by the Court of Appeal, stating that the terms of the contract are not stipulated, and therefore, everything is left to the discretion of the authorities. Legal uncertainty negatively affects the exercise of human rights in the field of healthcare and not always an individual can get effective protection of their rights in court. The authors of this study do not agree with the assessment of the Court of Appeal in the outlined case, believing that legislative shortcomings should not negatively

affect the implementation of human rights in view of Articles 3 and 8 of the Constitution of Ukraine.

Elements of the rule of law are the principles of equality and justice, legal certainty, clarity, and unambiguity of the rule of law, as otherwise cannot ensure its uniform application, does not preclude unrestricted interpretation in law enforcement practice and inevitably leads to arbitrariness (paragraph 2 of subclause 5.4 clause 5 of the motivating part of the Decision of the Constitutional Court of Ukraine No. 5-рп/2005 dated 22 September 2005[1]).

The study draws attention to the Decision of the European Court of Human Rights in the case "Fedulov v. Russia" [19], where the European Court of Human Rights recognised a violation of Article 1 of the Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms. The applicant complained that the authorities had failed to provide him with the free medicines he was entitled to in connection with his cancer treatment. Mr. Fedulov was diagnosed with cancer in 2007. He was entitled to free medication, in this case Bicalutamide, which he needed for 8-12 months. However, the pharmacy, which was intended to give him the medicine free of charge, provided it only once on these terms. In all other cases, he was informed that Bicalutamide was not available free of charge, but that he could purchase it at his own expense. In the following months, he paid 1,400 euros for treatment. He complained to the authorities and the courts about the lack of free medicines and sought reimbursement, but in February 2008 the district court dismissed his claim in full. The court found that the authorities involved, the St. Petersburg Health Insurance Fund and the St. Petersburg Health Committee, had done everything required by law. The applicant complained that he had not been provided with the medicines to which he was entitled under the law free of charge and that the authorities had not reimbursed him after he had had to purchase the necessary medicines at his own expense, basing his position on Article 1 of Protocol No. 1 (protection of property). The ECHR stated in its assessment that the parties did not deny that four times out of five the applicant had not been able to obtain the medication needed to treat his illness due to the lack of this medicine for distribution free of charge. Considering the finding that the applicant had a "legitimate expectation" that he would receive preferential assistance, the ECHR concluded that there had been an interference with the applicant's right under Article 1 of the First Protocol, and it is therefore necessary to determine whether this interference was justified.

The first and most important requirement of Article 1 of the First Protocol is that any interference by a public authority in peaceful possession should be lawful. As for the "law", Article 1 of the First Protocol refers to the same concept as the Convention, where the term is employed, and requires that the measure complained of be based on a sufficiently accessible and sufficiently precise domestic legal provision. Furthermore, the rule of law, one of the fundamental principles of a democratic society, is inherent in all articles of the Convention. So, the question of whether a fair balance has been struck between the requirements of the general interest of the community and the requirements

[1] Decision of the Constitutional Court of Ukraine in the case on the constitutional petition of 51 People's Deputies of Ukraine on the constitutionality of the provisions of Article 92, paragraph 6 of Section X “Transitional Provisions” of the Land Code of Ukraine (case on permanent use of land), No 5-рп/2005. (2005, September). Retrieved from https://zakon.rada.gov.ua/laws/show/v005p710-05#Text

of protection of fundamental human rights becomes relevant only after it is established that the intervention satisfies the rule of law and was not arbitrary.

In the present case, the ECHR notes that, although the applicant's right to the benefit in question was never in doubt, the domestic courts had, in fact, justified the refusal by reference to the lack of budgetary resources earmarked for that purpose by the St. Petersburg residents of this city for free medicine. Therewith, they did not invoke any legislative provision which would stipulate the refusal to provide the relevant benefit by any restrictions on budget funds, which made provision for any discretion on the part of the executive authorities to reduce or deny this right after reaching the budget allocation limit or any such provision that could provide legal grounds for such a conclusion. In this regard, it is noteworthy that in subsequent court decisions taken in proceedings on similar claims, it was clearly stated that the existing legal framework establishes the right of those who are entitled to the necessary medicines not only free of charge but also without any restrictions, and that the establishment of a maximum number of specific medicines per person or insufficient budgetary funding allocated to a particular region cannot serve as grounds for refusing to provide interested persons with medicines that are important for their lives.

The study of innovative legal constructions gives grounds to assert that legislative shortcomings, first of all vagueness and uncertainty of the legal essence of civil instruments, source gaps and lack of scientific interest, have already caused problems in law enforcement and, consequently, have violated human rights in healthcare.

CONCLUSIONS

Having studied the new legal constructions through the lens of judicial practice, their civilistic nature was clarified and recommendations were made to optimise the enforcement and administration of the law:

1. Law No. 2168-VIII is special, because it regulates the procedure for providing medical care at the expense of the State Budget of Ukraine under the medical guarantee programme. Therefore, the following conclusions are drawn: 1) when providing medical care under the medical guarantee programme, the patient's right to freely choose a doctor is limited by the choice of a primary care physician; 2) the choice of a doctor in the provision of other types of medical care under the medical guarantee programme is subject to numerous regulatory restrictions, which does not allow to fully feel the freedom of choice in the exercise of personal non-property right to medical care; 3) when providing medical care outside the programme, free choice must be provided on the basis of Articles 6 and 38 of the Fundamentals, which does not correlate with Article 24 of the Constitution of Ukraine.

2. The declaration on the choice of a doctor providing primary healthcare has the following legal significance: a) certifies the exercise of the right to freely choose a doctor; b) by its legal nature is not a transaction; c) is a legal fact that confirms the emergence of a natural person's status of a third party under the Agreement under the medical guarantee programme.

3. The contract under the medical guarantee programme on the legal essence is the contract on rendering of services. According to the principle of dichotomy, this contract consists of two parts: 1) in the part "customer – provider", it is a contract for the provision of services under public procurement; 2) in terms of rendering medical services

by the provider to the patient, it is a contract for the benefit of third parties; 3) is civil legal in nature.

4. Theoretical gap leads to problems of legal understanding in the application of Ukrainian legislation, which has a negative impact on the effectiveness of human rights protection in the field of healthcare, which can be clearly seen in the analysis of judicial practice.

5. The "legitimate hope" that arises in a person in the presence of regulatory guarantees is under conventional protection, as illustrated in the decisions of the ECHR, and to change the paradigm, a transformation of the law is required. The principle of the rule of law is guarded so that dissonance does not deepen and "legitimate expectations" through a guaranteed right does not depend on the lack of public funds.

The subject matter is multidisciplinary, important for both lawyers and healthcare professionals, therefore scientific intelligence should be spectral and in-depth in order to provide better scientific cognition of the analysed legal constructions, and thus develop a doctrine that will best protect human rights, including in the administration of justice.

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