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Assisted Reproductive Technologies as the Subject Matter of a Contract for the Provision of Medical Services Under Directive 2011/24/EU

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The article examines the legal nature of assisted reproductive technologies (ART) as the subject of a contract for the provision of medical services in the context of Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare. The key concepts of the Directive relevant in the context of the study are analyzed, such as "medical care", "cross-border healthcare", "patient rights", and the possibility of their application to contractual relations arising when receiving ART services in another state. The issue of qualifying ART services as planned medical care, which requires obtaining prior permission from the state insurer, is considered, and an attempt is made to outline the legal boundaries of such regulation. Separately, the study examines the contractual relations between the patient and the medical institution (institution) providing ART services, including issues regarding the subject of the contract, the definition of its parties, the scope of the obligations of the medical institution (institution) to the patient and the mechanism for protecting the patient's rights as such. The provisions of Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare are analyzed in terms of the legal regulation of ART services in Ukraine in the context of the adaptation of national legislation to EU standards within the framework of Ukraine's implementation of the Association Agreement. Sectoral conclusions and proposals are formulated regarding the possibility of improving the legal regulation of contracts for the provision of ART services in Ukraine, taking into account the European integration course, the requirements of EU legislation and the recodification of civil legislation.



KEYWORDS

assisted reproductive technologies, contract, provision of medical services, Directive 2011/24/EU, cross-border medical care, patient rights.



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Допоміжні репродуктивні технології як предмет договору про надання медичних послуг за Директивою 2011/24/ЄС

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У статті досліджується правова природа допоміжних репродуктивних технологій (ДРТ) як предмета договору про надання медичних послуг в контексті Директиви Європейського Парламенту та Ради 2011/24/ЄС про застосування прав пацієнтів у сфері транскордонної медичної допомоги. Аналізуються ключові поняття Директиви, актуальні в контексті дослідження, такі як «медичне обслуговування», «транскордонна медична допомога», «права пацієнта», та можливість їх застосування до договірних відносин, що виникають при отриманні послуг з ДРТ в іншій державі. Розглядається питання кваліфікації послуг з ДРТ як планового медичного обслуговування, що вимагає отримання попереднього дозволу держави-страховика, та зроблено спробу окреслити правові межі такого регулювання. Okремо в дослідженні розглянуто договірні відносини між пацієнтом та медичним закладом (установою), що надає послуги з ДРТ, у тому числі питання щодо предмета договору, визначення його сторін, обсягу зобов'язань медичного закладу (установи) перед пацієнтом та механізму захисту прав пацієнта як такого. Аналізуються положення Директиви Європейського Парламенту та Ради 2011/24/ЄС про застосування прав пацієнтів у сфері транскордонної медичної допомоги в частині правового регулювання послуг з ДРТ в Україні в контексті адаптації національного законодавства до стандартів ЄС в рамках виконання Україною Угоди про асоціацію. Сформульовано галузеві висновки та пропозиції щодо можливості вдосконалення правового регулювання договорів про надання послуг з ДРТ в Україні з урахуванням євроінтеграційного курсу, вимог законодавства ЄС та рекодифікації цивільного законодавства.



КЛЮЧОВІ СЛОВА

допоміжні репродуктивні технології, договір, надання медичних послуг, Директива 2011/24/ЄС, транскордонне медичне обслуговування, права пацієнта.

1. Introduction

The sphere of assisted reproductive technologies (hereinafter referred to as ART) is one of the newest and, at the same time, one of the most rapidly transforming branches of modern medicine, and, in its multidisciplinary nature, is also one of the most complex areas for legal regulation. Today, ART has become, for the most part, a widely available medical practice for the vast majority of the population, with services provided to patients in medical institutions (facilities) almost everywhere. As a somewhat controversial counterpart to the current situation, there is the emergence of the well-known phenomenon of “reproductive tourism”, the essence of which is the appeal of citizens of one country for ART services to medical institutions (facilities) of another country, which is usually due to several different reasons and circumstances (lower cost of services, more loyal rules of legal regulation of ART in general, a wider list of procedures and manipulations that can be provided, etc.). To date, there is no direct legislative prohibition in Ukraine on the provision of ART services to citizens of other countries, since in fact the only narrowly sectoral act in this area is the Order of the Ministry of Health “On Approval of the Procedure for the Application of Assisted Reproductive Technologies in Ukraine” [1], which contains a norm that foreigners may be the parents of a child born to a surrogate mother.

The problem of cross-border receipt of ART services in the European Union has become particularly relevant with the adoption of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare (hereinafter referred to as the Directive) [2]. The purpose of the said Directive is to regulate the rights of patients of EU Member States to receive medical care in other Member States and access to safe and high-quality cross-border medical care, to reimbursement of relevant costs from the social insurance system or the general healthcare system, etc. Since Ukraine, within the framework of the implementation of the Association Agreement between Ukraine and the EU, has undertaken obligations to adapt national legislation to EU legal standards, including in the field of healthcare, it should be noted that currently the legislation of Ukraine is only partially harmonized with the provisions of the Directive by developing a roadmap for its implementation for 2026-2027, including in terms of the procedure for providing and the corresponding list of cross-border medical services, the mechanism for reimbursement of costs and the maximum allowable amounts of such reimbursement [3, p. 350]. Under such circumstances, the question of extending the scope of the Directive’s provisions to ART services (including in the context of further harmonization with national legislation) and their qualification in the structure of contractual legal relations between the patient and the medical institution (institution) is logical.

2. Literature Review

The issue of legal regulation of ART services in EU legislation is the subject of quite active scientific discourse in the segment of foreign scientific research. One of the most famous fundamental works in the outlined area is the scientific study by G. Pennings, which comprehensively and systematically analyzed the legal and ethical aspects of ART [4] (including co-authorship with G. de Wert [5]). The fundamental principles of EU medical contract law, including the qualification of contracts for the provision of ART services and the main aspects of liability in this area, found their thorough analysis in the studies of A. de Paor [6] and A. Mulligan [7]. A significant scientific contribution to the study of the legal aspects of cross-border receipt of medical services as such in the context of the Directive and in the context of EU legislation in general was made by scientists I. Glenn Cohen [8], O. Golyner [9], S. de la Rosa [10], etc.

In more detail, the contractual aspects of the provision of ART services are examined in scientific works on medical law by E. Jackson [11]; a practical comparative legal analysis of the regulation of ART services by different EU Member States is contained in collective studies edited by L. Merete, N. Lykke [12], as well as S. Greer, T. Hervey, J. Mackenbach and M. McKee [13]. The interaction of the Directive with the practice of providing cross-border medical services is examined in the work of M. Wismar, W. Palm, J. Figueras [14] and others; the issue of cross-border telemedicine in the EU is discussed in the study of C. Campiglio [15].

At the same time, it should be noted that in domestic legal science, the outlined issues have not yet received comprehensive and systematic coverage, since the studies available today either analyze

the legal component of the issues of ART mainly from the perspective of family law, or conduct fundamental and sectoral scientific research in the field of adapting Ukrainian legislation to EU standards in the field of healthcare in general, without focusing the vector of attention specifically on the legal regulation of ART.

3. Problem Statement

The purpose of this article is to analyze the legal nature of RTD as the subject of a contract for the provision of medical services in the context of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare and to formulate conclusions and proposals for the appropriate legal regulation in national legislation, taking into account the European integration vector.

4. Methods and Materials

The methodology for studying the legal nature of the DRT as the subject of a contract for the provision of medical services in the context of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare is based on a combination of general and special research methods. When studying international legal norms and norms of national legislation, the formal-legal method was used. The comparative-legal method was used to outline the main aspects of the correlation of the provisions of domestic legislation with the requirements of international legal standards in the area under study. The formal-logical method was used to identify gaps and contradictions in the norms of current legislation, while at all stages of the work, analysis and synthesis techniques were also used.

5. Results and Discussion

Cross-border healthcare refers to healthcare received by a person outside their own Member State: EU citizens have the right to receive both healthcare in any EU country and, at the same time, reimbursement for such cross-border treatment in their own country. Various legislative instruments are used at EU level to ensure this fundamental right, one of which (together with Regulation (EC) No. 883/2004 on the coordination of social security systems and Regulation (EC) No 987/2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems) is Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, adopted on 9 March 2011. The provisions of the Directive facilitate cross-border cooperation, the recognition of prescriptions and the functioning of European Reference Networks (ERNs) [16, pp. 12-13]. The purpose of the Directive, as defined in Article 1, is to establish rules to facilitate access to safe and high-quality cross-border healthcare in the EU and to promote cooperation between Member States in the field of healthcare, while respecting the responsibility of Member States for the organisation and delivery of healthcare [2].

Article 3 of the Directive defines "healthcare" as medical services provided to patients by healthcare professionals for the assessment, maintenance or restoration of health, including the prescription, dispensing and supply of medicinal products and medical devices. This rather broad definition is important in the context of the subject of this study, as it covers not only the treatment of diseases in the narrow sense, but also a wider range of medical procedures aimed at "assessment, maintenance or restoration of health". The provisions of the Directive also define cross-border healthcare as healthcare provided or prescribed in a Member State other than the patient's state of affiliation. In general, the Directive is based on the fundamental principle that patients should be able to receive healthcare in any EU Member State and be reimbursed by their national healthcare system at the rate applicable to similar treatment in their own country. This principle was developed in a series of judgments of the European Court of Justice, starting in 1998, which established that the free movement of services also extends to healthcare [17]. The question of whether ART services fall within the definition of 'healthcare' under the Directive is therefore of paramount importance from the point of view of determining the legal regime of the relevant agreements. An analysis of the text of the Directive leads to the conclusion that ART should be considered as 'healthcare' within the meaning of the Directive, taking into account the following reasoning.

Thus, it should be noted that ART services are purely medical procedures (embryo transfer; gamete or embryo donation; surrogate motherhood; embryo reduction, etc. [1]), which are provided by qualified medical professionals in medical institutions (facilities). These medical procedures are used to solve the problem of infertility and assist individuals or couples in achieving pregnancy - this is a highly specialized field that is rapidly developing and combines reproductive endocrinology, embryology, genetics, and a personalized approach to patient treatment [18]. Therefore, the implementation of such procedures requires the availability of appropriate qualifications of medical professionals, appropriate medical equipment, licensing and permits, and is regulated by the medical law of the state providing such services. However, on the other hand, unlike standard medical services, the purpose of which is to restore the original state of a physically healthy organism (or the maximum approximation, taking into account the existing situation, to such a state), ART, on the contrary, is not aimed at treating infertility and does not treat it, and patients remain in their original state of health after the provision of ART services, i.e. from the standpoint of jurisprudence, we are talking about a slightly different qualification of such a procedure. However, it would be fair to focus on a sufficiently convincing argument in favor of qualifying ART services as “medical care” - the definition of this concept in the Directive includes, among other things, services aimed not only at “restoring” but also at “maintaining” the patient’s health (legal aspect). In addition, the World Health Organization has defined infertility as a health condition (as of November 2025), which is an additional confirmation of the position on the medical nature of ART services (medical aspect) [19].

Analysis of the provisions of the Directive allows for a conditional differentiation of two regimes for the provision of cross-border healthcare: (1) services that do not require prior authorization, and (2) scheduled healthcare, the provision of which outside the country of residence of a person may be subject to the requirement to obtain prior authorization (coordination) from the country of residence. Thus, in accordance with Article 8 of the Directive, Member States may establish a requirement for prior authorization for healthcare that involves at least one night of hospitalization in a hospital or requires the use of specialized and expensive medical infrastructure [2]. Procedures (manipulations) for the provision of ART services meet at least one of the above conditions: they require the availability of specialized equipment (for example, cryo-storage for freezing and long-term storage of biomaterial [20, p. 145]), and also provide for the possibility of hospitalization, including, for example, in the event of complications. That is, Member States may hypothetically require prior authorization for cross-border receipt of ART services, but, at the same time, the provisions of the Directive establish clear criteria for such requirements: they must be necessary, proportionate and not pose a threat to the free movement of services. As emphasized in European studies, Member States should publish a precise list of medical services subject to prior authorization, since the Directive does not specify how much time Member States can spend on adopting a decision on such authorization (it mentions a purely “reasonable period”, which also takes into account any emergencies related to the patient’s condition) [21, p. 10]. It would also be appropriate in the above context to mention the precedent judgment of the Court of Justice of the EU in case C-372/04, which confirmed that an unjustified delay in issuing an authorization for treatment abroad (or an unjustified refusal) constitutes a violation of the right to freedom to provide services [22]. In terms of the analysis of ART services, it is considered important to resolve the issue of a possible refusal of the state-insurer to grant the appropriate permit because the provision of a certain ART service is prohibited (restricted) in this state, but at the same time is absolutely permitted in the state of treatment (for example, the well-known situation with surrogacy, etc.).

As for the direct characteristics of the contract for the provision of ART services, such a contract should be considered a type of contract for the provision of medical services. In scientific research, a contract for the provision of medical services is interpreted as a contract whose subject is the performance by a medical professional of certain actions (provision of services), and not the achievement of a specific result [23, p. 62]. Such clarification is important precisely in the context of ART services, since a medical institution (institution) undertakes to perform the relevant medical procedures and/or manipulations, but cannot guarantee the occurrence of a positive result, for example, the occurrence of pregnancy. In fact, the subject of a contract for the provision of ART services is a complex of several interrelated procedures: the provision of advisory and information services; medical examination of the patient; preparation for the procedure and its direct conduct; medical support after the procedures, etc., each of which can be either the subject of a separate contract, or can be included in a single contract for the provision of ART services.

The parties to an agreement on the provision of ART services are, as a rule, the patient (or a couple of patients) and the medical institution (facility) providing ART services. The Directive defines several patients' rights that directly affect the content of the contract for the provision of ART services, one of which is the patient's right to receive information on quality and safety standards (the "right to information" - (Article 4(2)(b)) [2]. The medical institution (institution) is obliged to provide the patient with complete and accurate information about the procedure/manipulation, its possible risks, conditions, and cost of the services to be provided, and failure to provide such information or provision of inaccurate information is not only a breach of the terms of the contract, but may also have relevant consequences in the form of liability. In turn, the obligation to obtain informed consent from the patient before performing the procedure is the obligation of the medical institution (institution), which in the context of ART acquires important significance, since the procedure usually concerns both partners and involves making decisions that have long-term, vital legal consequences (for example, cryopreservation [24]).

Furthermore, if we are talking about cross-border relations, then the party to the contract for the provision of ART services The DRT, accordingly, is a medical institution (institution) of a foreign state, and in the event of a question of applicable law, the provisions of Regulation (EC) No. 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I) should be followed. According to the provisions of the said Regulation, in the absence of an agreement between the parties on the choice of law, the law of the state in which the medical institution provides the services shall apply to the contract for the provision of medical services [25]. However, at the same time, the issue of liability of a medical institution (institution) for improper provision of services with DRT in a cross-border context is extremely complex, since it involves the interaction of legal systems of different countries. The Directive, in turn, stipulates that the state providing treatment is obliged to ensure the availability of protection mechanisms for patients in the event of harm caused when receiving cross-border medical care (Article 4(2)(c)) [2].

Ukraine is one of the few countries in Europe where the field of ART (including the repeatedly mentioned surrogacy, which is legally prohibited in several countries around the world) is generally regulated much less imperatively than in most EU member states, which, accordingly, causes the growth of "reproductive tourism" to our country. Thus, the main regulatory legal acts regulating ART services in Ukraine today are the Civil Code of Ukraine, the Family Code of Ukraine, the Law of Ukraine "On the Fundamentals of the Legislation of Ukraine on Healthcare", the Order of the Ministry of Health of Ukraine "On Approval of the Procedure for the Application of Assisted Reproductive Technologies in Ukraine", etc. In the context of adapting domestic legislation to EU legislation, it should be noted once again that the Directive is part of the *acquis Communautaire* in the field of healthcare, and the standards defined by the Directive are a guideline for further reforming national legislation in the field of cross-border medical services. It should be noted that currently the current domestic legislation in the field of ART services contains several gaps in terms of the standards introduced by the Directive: there is no special sectoral law on ART, which leads to fragmentation, contradictions and uncertainty of legal regulation (currently this issue has been resolved only at the stage of the draft law); mechanisms for protecting the rights of patients (both citizens of Ukraine and foreigners) and informing them during ART procedures are insufficiently developed and transparent.

6. Conclusions

It should be noted that ART services are covered by the concept of "medical care" within the meaning of Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, since they correspond to the definition of medical services enshrined therein, which, in turn, gives grounds to consider it possible to extend to cross-border relations for the provision of ART services the entire set of rights of the parties outlined in the Directive. ART services can also be qualified as medical care when interpreting the provisions of Article 8 of the Directive, which provides grounds for the introduction by Member States of a requirement for prior authorization for cross-border receipt of such services.

For Ukraine, bringing the provisions of national legislation into line with the standards of the Directive is an urgent need both to ensure proper legal protection of patients, including foreign citizens, and for the further competitiveness of domestic medical institutions (facilities) on the EU market.

Thus, further scientific research in the outlined area should focus on a comparative analysis of the legal nature of contracts for the provision of ART services in the EU Member States to develop a hypothetical single contractual model, as well as on the development of further effective mechanisms for harmonizing Ukrainian legislation with the *acquis Communautaire* in the field of cross-border medical care.

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