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Formation of Patient's Consent Doctrine in the Current Legislation of Ukraine

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Abstract: The purpose of the article is to study scientific and practical aspects of legal regulation of patient's informed voluntary consent in Ukrainian civil and special medical legislation. The subject matter of the research is the formation of the patient's consent doctrine in the current legislation of Ukraine. The authors have studied the importance of respect for patient's autonomy in modern medical ethics and law, which is embodied in the requirement to provide consent for any medical intervention. It has been proved that the rule of patient's informed voluntary consent is a modern legal standard and a legal prerequisite for any medical intervention. Its components have been characterized: patient's awareness about the state of health and offered treatment, the choice of treatment methods, the possibility for patients to refuse what they may consider as inappropriate or unnecessary treatment. The main principles of the Ukrainian doctrine of patient's informed voluntary consent in the form of the doctrine of informed voluntary consent have been defined; the key regulatory legal acts that initiated the implementation of the doctrine of informed voluntary consent have been distinguished; the nature and reasons for making amendments to the legislation have been analyzed; an assessment of the quality of such amendments has been provided; areas for further development of Ukrainian doctrine and legislation in the light of recognized European standards regarding the protection of human rights and dignity in the field of medical care have been suggested.

Key Words: the right to human dignity, medical legal relations, patient's autonomy, informed voluntary consent, emergency medical intervention, representation of minor patients

I. INTRODUCTION

The concept of human rights and dignity is a key component of the research and legal regulation of legal relations on providing medical services. All human rights in the Western European tradition of private law derive from their natural dignity, which is interpreted in the modern legal context with the help of such notions as personality, inherent value, inviolability, physical and mental integrity, freedom of choice. The totality of the indicated factors form a paradigm of moral autonomy of a person as a fundamental social and legal value.

A significant step towards the formation of the European concept of human rights and dignity was the conclusion of the Convention for the Protection of Human Rights and Fundamental Freedoms [1]. Regarding the legal interpretation of the concept of "human dignity", the European Court of Human Rights noted that "the very essence of the European Convention is to respect human dignity and freedom, and the concepts of identity and personal autonomy are important principles underlying the interpretation of guarantees of their observance ... when providing medical care". Therefore, "forced medical intervention without the consent of a legally capable patient is an interference into his right to personal integrity and an infringement of the rights guaranteed by the Art. 8 of the European Convention" [2].

A special aspect of respect for human dignity is the legally established human right to make important personal decisions within private law relations regarding medical intervention based on personal worldview and value beliefs. Therefore, such absolute values as dignity, integrity, inviolability in the field of medical care are interpreted through the concepts of freedom, identity and autonomy, and provide for the legal opportunity for a person to independently use and dispose own body, certain organs, body parts and allow or limit access to them. Legal protection of a patient's dignity in the field of medical care is based on the principle of informed voluntary consent.

This basic principle acquires legal force with the help of the system of special legal means that legally ensure identity and moral autonomy of a patient within private law relations in the field of medical care provision [3].

The purpose of the article is to study scientific and practical aspects of legal regulation of patient's informed voluntary consent in Ukrainian civil and special medical legislation. The object of the article is legal regulation of patient's informed voluntary consent to medical intervention, and the subject matter is the formation of patient's consent doctrine in the current legislation of Ukraine. The objectives of the article are: retrospective analysis for the formation of patient's consent doctrine; research of the main stages of the relevant legislation's formation; identification of positive tendencies, existing conflicts and gaps; elaboration of suggestions for further development of Ukrainian doctrine and improvement of legislation in the light of European legal standards. The main principles of the Ukrainian doctrine of patient's informed voluntary consent in the form of the concept of human rights and dignity have been defined as a result of the conducted research; the key regulatory legal acts that initiated the implementation of the doctrine of informed voluntary consent have been distinguished; the nature and reasons for making amendments to the legislation have been analyzed; an assessment of the quality of such amendments has been provided; areas for further development of Ukrainian doctrine and legislation in the light of recognized European standards regarding the protection of human rights and dignity in the field of medical care have been offered.

II. MATERIALS AND METHODS

A. LITERATURE REVIEW

The legal nature of patients' rights, certain aspects of informed voluntary consent and refusal of medical intervention were studied in the works of such Ukrainian scholars as G. Myronova [3]–[9]. The institution of patient's advance directives has recently attracted the attention of Ukrainian researchers, who offer to eliminate the gaps in national legislation and to enshrine the institution of previously expressed wishes in the legislation [10]-[12]. The problem of advance directives in the field of health care is widely and in detail discussed in the European scientific community in various aspects: regarding the implementation of patient's autonomy [13]; specifics of observing the ethics of autonomy in caring for the dying [14]; the importance of autonomy as the ability to make independent rational choice for patients receiving palliative care [15]; special regime of previous psychiatric directives [16].

B. METHODOLOGY OF THE STUDY

The methodological imperative of the research forms the concept of private law of the Western European tradition,

the recognition of human rights and dignity, which form the doctrinal basis for research and legal regulation of relations on providing medical services. The application of the dialectical method contributed to a comprehensive study of the doctrine of patient's informed voluntary consent to medical intervention both in the aspect of its formation and development and in the aspect of complete coverage of legally important elements. The method of retrospective analysis made it possible to reproduce the key elements of patient's consent doctrine in the aspect of their formation and development, to identify the factors of certain regulatory constructions and their relationship with the logic of the movement of civil and medical legislation. Analytical and comparative analysis of Ukrainian legislation was carried out by using the comparative method for the purpose of consistency between certain acts, as well as the compliance with the principles and norms of applicable EU law and the legal positions of the European Court of Human Rights.

III. RESULTS AND DISCUSSION

A. PRIORITY PRINCIPLES OF THE UKRAINIAN HEALTH CARE SYSTEM

The world has undergone crucial changes during the last few decades in the doctrinal approaches to the legal regulation of providing medical care; the paternalistic approach had been replaced by the principle of patient's autonomy, which was subsequently established in the form of legally binding rules. First, it happened at the international and legal level, and then gradually in the national law of the countries of Western Europe and North America. Respect for patient's autonomy is currently crucial in modern medical ethics and law and is embodied in the requirement of informed consent for any medical intervention. It certainly includes the ability for patients to refuse what they may view as inappropriate or unnecessary treatment when the burden of treatment outweighs any benefits.

The Historical Resolution of the Verkhovna Rada of Ukraine [17] enacted the Law of Ukraine "Fundamentals of Ukrainian legislation on health care" (hereinafter – "Fundamentals") [18], which fulfilled the important mission of the main act by regulating relations in the healthcare sector of the independent Ukrainian state. This outstanding document of Ukrainian law-making was from the very beginning aimed at embodying recognized universal human values in the national context. The observance of human and civil rights and freedoms; humanistic orientation and priority of universal human values; equality of citizens, democracy and universal access to medical care were declared as priority principles of Ukrainian health care system.

The concept of patient rights, which are derived from the fundamental human rights declared in the leading international and legal acts of our time has been already laid down in the first edition of the Law of Ukraine "Fundamentals" [19]. The Article 38 enshrines the right of every patient to freely choose a physician and a state medical and preventive institution. Patients according to the Art. 39 acquired the right to get medical information in an accessible form, to familiarize themselves with the history of their illness and other medical documents. The declarative nature of these norms was obvious from the very beginning, because patients of Ukraine could not exercise their rights in practice for some time because of the lack of enforcement mechanisms. However, an important first step in articulating the rights of patients in accordance with internationally recognized standards in the Ukrainian legal space has since been made.

The rule of consent from the very beginning became a core element of the concept of patient rights guaranteed by the Ukrainian state. The main components of patient's informed voluntary consent during the provision of medical care were establishedIn in the first version of the Art. 43 "Consent to medical intervention". Since then, the elements of the doctrine have significantly changed only twice in response to the demands of the time. Such a healthy conservatism of the basic legal construction testifies to the correct choice of the initial coordinate system, where further movement took place to improve, develop and fill the concept with more and more qualitative and adequate regulatory content to new realities.

We should analyze four elements of the consent rule in their retrospective development and prospective direction of further improvement: criteria for legality of patient's informed voluntary consent; specific features of exercising the right to refuse from medical intervention; the legal regime of providing consent in terms of urgent (emergency) medical care; representation of a patient in legal relations regarding the provision of consent to medical intervention.

B. THE RULE OF THE INFORMED VOLUNTARY CONSENT IN THE LEGISLATION OF UKRAINE

The first edition of the Law of Ukraine "Fundamentals" of 1992 [19] laid down the doctrinal framework for the entire system of patient rights in the Ukrainian legal tradition. The rule of patient's voluntary informed consent became the basis of the legality for providing medical care. The legal limit of patient's consent is set at the age of 15 years, or when the court recognizes an individual as legally incapable, or the impossibility of informing about own decision. Therefore, the consent under the provision of medical care acquires legal force in terms that a patient reaches the age of 15 years and has civil legal capacity. In urgent cases, when there is a real threat to a patient's life, the consent of a patient or his legal representatives is not required for medical intervention.

Further processes of improvement and legal polishing of norms took place in the course of amending certain norms of general and special civil legislation. The next important revision with significant amendments in the regulation of patient rights took place in regard to the introduction of the Civil Code of Ukraine in 2003. The Law of Ukraine "On Amendments and Revocation of Certain Legislative Acts of Ukraine in Connection with the Adoption of the Civil Code of Ukraine" [20] introduced amendments to the Articles 38, 39, 43 of the Fundamentals, which harmonized the relevant norms with the civil law doctrine of personal non-property rights ensuring the natural existence of individuals. According to the new edition of the Fundamentals [21], every patient who has reached the age of 14 and who has applied for medical assistance has the right to freely choose a physician and choose treatment methods in accordance with the physician's recommendations. The Article 43 was strengthened by the right to a refusal: "a patient who has acquired full civil capacity and is aware of the importance of own actions and can control them, has the right to refuse from treatment".

The construction of the right to medical information has undergone significant changes. Patients have the right to receive reliable and complete information about own state of health, including access to the relevant medical documents related to the health. The legislator added separate Article 39-1 "The right to secrecy about the state of health", where introduced a progressive novel about the legal construction of medical secrecy, which covers information about the fact of applying for medical information, diagnosis and any other information obtained during a medical examination. The Article 39-1 also introduced an important ban on requesting and providing information about a patient's diagnosis and treatment methods at the place of work or study.

Despite the timeliness and expediency of most of the innovations, unfortunately, the amendments of 2007 created a fundamental conflict of legislation existing till now. A patient has the right to choose a physician, a health care facility, and treatment methods from the age of 14, but the right to information about health and treatment methods arises only upon reaching the majority age.

C. DEVELOPMENT OF THE INFORMED VOLUNTARY CONSENT DOCTRINE AND ITS SHORTCOMINGS

Part 2 of the Art. 43 of the Fundamentals was set out in a new edition in 2013 as a result of the adoption of the Law of Ukraine "On Emergency Medical Aid" [22]. According to the new edition, the consent of a patient or his legal representative for medical intervention is not required only in case of signs of a direct threat to the patient's life, provided that it is impossible to obtain consent for such intervention from the patient himself or his legal representatives for objective reasons [23].

The significance of the new edition is the fact that it has finally corrected the ambiguity of the previous wording, which seemed that in urgent cases there was a derogation from the rule of patient's voluntary informed consent for medical intervention. Any medical intervention aimed at saving life was considered justified, even when there was no consent of a patient capable of expressing it. Physicians were assigned a corresponding duty to perform medical intervention without the patient's consent in urgent cases, if there was a real threat to the life. Such an essentially incorrect interpretation contributed to the distortion of the consent rule, part of which is the right of an adult legally capable patient to refuse from any medical care, including life-necessary care. Therefore, several clarifications in the disposition of the Article under the new edition corrected this original ambiguity. From now, the consent of a patient or his legal representative for medical intervention is not required only if there are signs of a direct threat to the patient's life, provided by the fact that it is impossible to obtain consent for objective reasons. However, these positive changes were not duplicated in the Civil Code of Ukraine. Thus, the specified conflict between two methods of regulating the same relations still exists.

As a result of recent significant changes, we currently have the following construction of the patient's right to voluntary informed consent while providing medical care. A patient who has reached the age of 14 has the right to freely choose a physician, methods of treatment and to consent while the provision of medical care. A patient who has reached the majority age has the right to receive reliable and complete information about own health state, including access to the relevant medical documents related to own health. A patient who has acquired full legal capacity and is aware of the importance of his actions and can control them, has the right to refuse from treatment.

A common place that is constantly the focus of scholars attention is conflicts in the current civil legislation related to the legal regulation of relations involving minors from the age of 14. The legal norm stipulating the need to obtain consent from a minor over 14 years conflicts with the norm that the same minor patient does not have the right to receive complete and reliable medical information and the right to refuse from medical intervention. In this case, the patient's age should be consistently related to the defined scope of his legal capacity and all the Articles concerning this subject matter should be harmonized. Thus, the age of 14 years in civil and family legislation is the limit when the law recognizes the independent legal actions of minors in some areas as legally qualified ones. Legislation has formed an established regulatory concept of incomplete civil legal capacity, which provides for the granting of a wide range of powers to a minor who has reached the age of 14. We consider it expedient and logical in this context to provide an individual from the age of 14 with the legal opportunity to independently exercise the full range of rights in the field of medical care: regarding the choice of a medical institution, a physician, methods of medical intervention in accordance with the physician's recommendations, regarding consent to medical intervention and refusal from it. Such a reasoned approach will play an important role in establishing legal certainty of the rules of civil regulation, ensuring the stable status of participants in civil relations and, to a certain extent, protection against abuse.

Despite the existing shortcomings, the regulatory construction of the consent rule plays an important positive role in the formation of the Ukrainian health care system oriented to humanistic European values. After all, the right to consent to medical intervention is one of the most important human and patient rights in the European jurisdiction. It is based on the recognition of a person's fundamental rights to dignity, inviolability, physical and mental integrity, and autonomy of the human personality. This important relationship of

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universal human values with the right to consent to medical intervention is enshrined in leading international human rights documents and in Ukrainian acts of civil and medical legislation.

D. PERSPECTIVE AREAS FOR IMPROVING PATIENT'S CONSENT DOCTRINE DURING THE RENEWAL OF THE CIVIL LEGISLATION OF UKRAINE

In our opinion, there are perspectives for further development in the aspect of implementing the norms of international treaties that Ukraine acceded. In particular, the next longawaited stage of improving the legislation regulating the patient's right to consent in the provision of medical care is related to plans to update the Civil Code of Ukraine and Ukraine's ratification of the Convention on the Protection of Human Rights and Dignity regarding the Application of Biology and Medicine [24]. As a result of the ongoing professional discussion regarding the ways to update special legislation, the main expert positions were formed concerning the construction of the rule of a patient's consent as a reflection of the doctrine of human rights and dignity in the field of medical care.

A separate legally important issue that requires further regulatory definition is the institution of representation of minors within legal relations with health care institutions. For the proper legal regulation of the provision of medical care to minors, it is important to have a clear legal distinction between persons who can act as their legal representatives.

The answer to the question about legal representatives of minors can be found from a generalized analysis of the provisions of civil and family legislation. The Article 242 of the Civil Code of Ukraine provides the general concept of the institution of legal representation: "1. parents (adoptive parents) are the legal representatives of their juvenile and minor children. 2. the guardian is the legal representative of a minor and an individual recognized as incapable". According to the Article 43 of the Law of Ukraine "Fundamentals", in relation to patients under the age of 14, medical intervention is carried out with the consent of their legal representatives.

The range of persons who are legal representatives of children, orphans and children deprived of parental care, as well as their rights and obligations are defined in the Family Code of Ukraine [25]. Parents, guardians, adoptive parents, foster parents, as it is stipulated in the Family Code, are the legal representatives of a minor without special powers, including in legal relations with health care institutions and medical employees. Therefore, these persons are endowed by law with representative functions and parental responsibility. They have the right to decide the issue of choosing a medical institution, a physician and treatment methods, to receive medical information about the minor, to give consent and refusal to provide medical assistance to their child.

The legislation also gives certain powers to family members and relatives. Chapter 21 of the Family Code of Ukraine defines the legal status (rights and obligations) of other family members, which include the following blood relatives and family members: grandmother, grandfather, great-grandmother, great-grandfather, full-blood or halfblood brothers and sisters, stepmother, stepfather. The Article 68 of the Civil Code of Ukraine defines the range of close relatives – parents, children, brothers, sisters.

Therefore, the legislation defines the range of persons who have the right to represent the child in certain legal relationships without special powers, due to the fact that they are related to the minor by family relations. We consider it as a consistent and expedient step to extend the authority of the representative of a minor's interests in legal relations with health care institutions to family members and relatives, in case there are no parents, guardians, adoptive parents, foster parents, in the following priority sequence: stepmother, stepfather, full-blood or half-blood adult brother or sister, grandfather, grandmother, great-grandfather, greatgrandmother.

In case when persons with parental responsibility wish to appoint a specific person to whom they entrust the implementation of the rights and interests of their child in the provision of medical care for a specified period of their absence, they can enter into an appropriate agreement with an authorized person and record their will in a power of attorney in accordance with the rules of the Articles 244, 245 of the Civil Code of Ukraine.

With regard to the right to refuse from medical care, legislation and enforcement should clearly recognize and uphold the rule that a competent patient has the right to refuse from any medical care. After all, the right of an adult with legal capacity to consent is absolute and includes the right to refuse from consent or from medical intervention as a necessary element, even from one aimed at life support [4].

Regarding the regulation of emergency situations (emergency or urgent intervention), legislation in this part needs comprehensive improvement based on the legal positions of the European Court of Human Rights, principles and norms of the European Convention, of the Oviedo Convention. The analysis of the specified legal documents gives reason to assert that the components of the legal mechanism for providing medical care in emergency circumstances, when consent cannot be obtained from the patient himself for objective reasons, are the following rules: medical intervention should be limited to measures that are exclusively necessary from a clinical point of view to avert real and unavoidable threats to the patient's life and health; the patient should still be involved in the decision-making process through previously expressed wishes.

With regard to such a new legal instrument for clinical decision-making as the preliminary orders enshrined in the Article 9 of the Oviedo Convention, the European Court of Human Rights has formulated basic principles that must be taken into account for further improvement of the national legislation of Ukraine in this area. In the decision Lambert and Others against France [26], the European Court of Human Rights formulated the following position: when two conventional rights are opposed – the right to life with

the corresponding duty of the state to protect life under the Art. 2 of the European Convention, on the one hand, and the right to personal autonomy expressed through advance orders to refuse from treatment, which is protected by the Art. 8 of the European Convention, in such a contest "respect for human dignity and human freedom may prevail"; "in case of the lack of prior orders, the dignity of a person is interpreted in terms of the predominance of the value of life". However, the European Court of Human Rights stated in its Decision "Berke aganist the United Kingdom" [27], that the patient's previous requests for treatment in future unknown circumstances are not binding, because they are subject to evaluation in the light of good medical practice in regard to actual medical intervention.

Therefore, the next step should be the formation of a coherent, non-controversial concept of the consent rule in the updated civil legislation of Ukraine with the following basic elements: a patient from the age of 14 has all rights to choose treatment methods, a health care institution, to informed voluntary consent to medical intervention; a legally capable adult patient has the right to refuse from any medical care; a patient has the right to make advance directives regarding future medical interventions and appoint a health care proxy. Such amendments are aimed at eliminating the shortcomings of the current legislation, implementing European standards of patient rights and ensuring effective legal protection of human rights and dignity in legal relations for the provision of medical services.

IV. CONCLUSION

Formation of national legislation starting with the declaration of Ukraine's independence was aimed at embodying recognized universal human values in the national context. The priority principles of Ukrainian health care were declared as the observance of human and civil rights and freedoms; humanistic orientation and priority of universal human values; equality of citizens, democracy and universal access to medical care. The first edition of the Law of Ukraine "Fundamentals of Ukrainian legislation on health care" has already laid down the concept of patient rights, which are derived from the fundamental human rights declared in the leading international legal acts of our time. The rule of consent from the very beginning became a core element of the concept of patient rights guaranteed by the Ukrainian state.

Perspectives for further improvement of the Ukrainian doctrine of patient's consent are related to plans to update the Civil Code of Ukraine and Ukraine's ratification of the Oviedo Convention. The main expert positions regarding the construction of the patient's consent rule as a reflection of the doctrine of human rights and dignity in the field of medical care were formed as a result of professional discussion concerning the ways to update special legislation. Certain legally important issues requiring further regulatory definition are related to the regulation of the absolute right to refuse from medical intervention, as well as to the institutions of representation of minors and legally incapable adults in medical legal relations.

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CONFLICTS OF INTEREST

No conflicts of interest have been declared by the authors.

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