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LEGAL REGULATIONS ON PATIENT'S RIGHT TO REFUSE MEDICAL TREATMENT

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REZUMAT. Reglementări legale privind dreptul pacientului de a refuza tratamentele medicale. Refuzul tratamentelor, a intervenţiilor de către un pacient este o realitate a practicii medicale, care duce deseori la dileme etice datorită conflictului dintre datoria medicului de a trata pacientul şi cel de a-i respecta dreptul la autodeterminare. Tema aceasta este importantă şi actuală prin faptul că pacientul secolului al XXI-lea tinde să decidă şi să acţioneze în mod autonom, într-un mod mult mai accentuat decât o făceau predecesorii săi, iar coordonatele relaţiei medic-pacient sunt regândite şi fundamentate şi pe alte criterii decât cele clasice. Astfel, este nevoie de o bună descriere, de o capacitate de analiză şi de o putere de sinteză a informaţiilor şi a argumentelor pentru a cunoaşte modul optim de acţiune şi de a proceda în consecinţă, cu scopul de a identifica punctele neelucidate, problematice. Scopul acestui articol este acela de a prezenta şi de a analiza modalităţile de implementare a dreptului la autonomie al pacientului conform reglementărilor legale internaţionale şi naţionale în vigoare, printre care şi dreptul de a refuza tratamentele.

Cuvinte-cheie: *refuzul tratamentelor, autonomie, consimţământ informat, refuz informat.*

ABSTRACT. Refusing treatments, interventions by a patient is a reality of medical practice, which often leads to ethical dilemmas because of the conflict between the duty of the physician to treat the patient and the patient s right to self-determination. The topic is important and actual, because the patient of the XXI century tends to decide and act autonomously, much more pronounced than their predecessors, and coordinates doctor-patient relationship are redesigned and based on other criteria than the classic ones. Thus, it needs a better description, capacity for analysis and synthesis information and arguments in order to know how is best to proceed and to identify points unclear or problematic. The aim of this paper is to present and to analyze how patient's right to autonomy is implemented in international and national legal regulations in force, including the right to refuse treatment.

Keywords*: treatments refusal, autonomy, informed consent, informed refusal.*

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INTRODUCTION

In some cases of the medical practice exercising this profession is limited due to patient's decision not to join the proposed treatment. Informed consent is a patient's right required before starting medical act. It is actually a choice, an informed choice between two possibilities: acceptance or rejection of the proposed treatment or consultation by a medical doctor. Principles of medical ethics assume that each person is respected as a value in itself, and this respect assumes the recognition of the individual autonomy. The medical ethics recognizes the fundamental principle of patient's autonomy, which in practice should be combined with other principles: beneficence, nonmaleficence and equity (1). From the legal point of view, the principle of autonomy translates as the patient's right to self-determination. He/she has the right to be informed, to act according to his/her will and faith, should not benefit from treatment if it decides so. Internationally this right of the patient is known under different names, and in the domestic Romanian legislation, the patient has the right to refuse treatments, including the lengthy and expensive ones, even when the refusal will result in death (2). In the following paragraphs we will present the international and national context on the right of refusing treatments and its consequences in the legal and medical practices.

INTERNATIONAL ENVIRONMENT. DELIMITING TERMS

1. The individual's right to self-determination

Patient's autonomy is protected by his/her right to self-determination, a concept introduced in the Lisbon Declaration on Patients' Rights, first in 1981 (3). This right was adopted by the international law and practices and refers to a patient who can freely decide to participate or not in a clinical trial or a medical act, and within the medical act to accept or to decline the proposed medical interventions. He/she has the right to take part in the therapeutic decision, which is conditioned by the Informed Consent. The right to self-determination is regulated only for those who, in the legal sense, are able to take a decision, to make a free choice. The factors that must be evaluated to determine the ability of making an informed decision are: understanding consequences of the decision, the patient's condition when he/she is taking the decision (ex. the terminally ill) and the process of the decision (4, 5).

2. Patient's right to treatment

The Universal Declaration of Human Rights (1948) in the article 25 provides the right of all persons to health care: "Everyone has the right to a

standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control" (5). This right is taken also by the Romanian legislation. Thus, the Romanian Constitution stipulates in the article 34 "the right to protecting the health" (6). The Law no. 46/2003 regarding patient rights, updated in 2014, provides, in the chapter 6, articles 29-36, the patient rights to treatments and health care (7).

3. Patient's right to refuse treatments

The Helsinki Declaration on Ethical Principles for Medical Research Involving Human Subjects adopted in 1964 stipulates in the article 26, for the first time in a formal framework and unanimously, the patient right to refuse treatment, with a specific purpose, the experimentation. The statement was made under the influence of the Nuremberg trials, where defendants of Nazi Germany were convicted and sparked discussions that impacted on the development of international criminal law, resulting in the Universal Declaration of Human Rights (8). The Helsinki Declaration provides the right to information of the subject, prior the experiment, giving him/her objective information about methods, benefits and dangers. The subject must be informed on his/her right to refuse participation in experimentations, on the possibility of abandoning anytime the clinical studies. Then he/she gives the free and informed consent to the medical doctor or researchers. In this process, the physician should pay particular attention to the possibility that the subject should not be coerced or forced to consent (9).

Later, in 1984 it was adopted the European Charter of Patients' Rights, which states that: "A patient's right to be informed about the diagnosis, therapy and prognosis". Another legal framework is the New York City Health and Hospital Corporation "Patient Rights", which establishes the right of the patient "to accept and refuse (in terms of correct) treatment and to participate in his election. In case of refusing treatments proposed by the physician, the patient should be advised of possible medical consequences of this refusal" (1). The law provides the right of patients to refuse treatment in the most parts of the world, a special question being the limited denial. The Oviedo Convention on the Protection of Human Rights and Human Dignity to the Application of Biology and Medicine of the Council of Europe adopted in 1997, the article 5 states besides respecting patient's autonomy the patient's right to receive information or to refuse to receive information, and the right to

withdraw consent previously given "data subject may at any time withdraw their consent freely" (10).

4. Forms of treatment refusal

The right to the Informed Consent includes also the right to informed refusal. Such refusal shall be stated under the laws of the country, in writing, by signing a standard form of assuming the decision. If the patient wants to dispose of the right to self-determination when he/she became incompetent to make decisions, he/she can draw up a living will or an advance directive (4), as a plan of further treatments.

Advance directives

Advance directives are documents that people, as future patients will manifest in advance, expressing their will to not receive certain treatments that would aim maintaining them alive (11). Basically, we are talking about refusing treatments or medical interventions that the future patient deemed useless or dangerous or unwilling to undergo such interventions, such as, for example, transplantation of an organ or the amputation of a member. The Oviedo Convention (1997) provides in the article 9, advance directives as "previously expressed wishes". Thus, "when the patient is not in a state to enable it to express their will there will be taken into account previously expressed wishes relating to a medical intervention". In Romania there is no specific law regulating advance directives. But Romania has ratified the Oviedo Convention of the Council of Europe (1997) by the Law no. 17/2001, so the text of the Convention is the benchmark for medical practice in Romania. The Deontology Code of Physicians (2012) also states in the article 16 the implied consent that "in the interests of the patient are valid and will be taken into account authorizations and wishes expressed previously regarding a medical intervention by a patient when at the new intervention it is not in a state to afford to express will or if the medical by nature has a specific sequence and repeatability" (13). Advance directives can be used only by patient who was once competent, and has, usually, two forms: drawing up a living will or delegating someone it trusts to decide in its place (14). Controversies and counter-arguments of this right are brought because the patient decides in some circumstances that could be very different when these documents are implemented or taken into account by physicians or close relatives. Some argue that the person who decides is no longer the same person at the time of the implementation will. (4)

THE RIGHT TO REFUSE TREATMENTS IN THE ROMANIAN LEGAL CONTEXT

1. Regulations concerning the doctor-patient relationship. Rights and Obligations of Parties

The relationship between the doctor and the patient starts by requiring the doctor (medical services) by the patient. To be born this relationship, it is legally required that the doctor accept to see the patient. In legal terms, medical staff and patient agreement is a covenant between the two parties. This relationship is not a contract in the traditional sense, but because it is an agreement of wills between two sides, according to article 942 of the Romanian Civil Code, it is a kind of contract. To be born this contract, the first step is done by the patient, who must see Primary Medical Assistance Service, which in turn gives access to the secondary care, of the medical specialist. The doctor will make contract offer, the second step being that the patient is accepting the offer. Only by written request from the patient may be arised healthcare contract. In Romania, the National Health Insurance's unique ticket fulfills the role of reference document acknowledging the request of the person that requires health services. The healthcare contract needs four key elements in order to be valid: the capacity of the parties to consent, an object of the contract and a cause (13). The Law No. 95/2006 on Healthcare Reform, republished in 2015, provides in the article 649 align. (3) that the information given to the patient must refer to: diagnosis, nature and purpose of the treatment, the risks and consequences of the proposed treatment, viable treatment alternatives with risks and consequences, the prognosis without treatment (15). The medical doctor incurs with the patient an obligation of means, not of results, and on patient's side paying medical fees will be the object of the contract. Exceptions to the birth of such contract are described in situations where the patient's decision-making capacity is absent or partial damaged, and the patient needs a legal guardian. Also medical emergencies are a particular case (13).

2. Interrupting doctor-patient relationship

According to Law no. 95 of 2006, the article 653, the relationship between physician and patient could be interrupted in the following situations:

a. once the disease is cured,

b. by the patient or

c. by the doctor, only in two specific situations, such as:

(i) The patient is sent to another doctor, providing all the medical data obtained, which justifies the assistance of another physician with competent skills;

(ii) The patient manifested hostility and/or disrespectful towards his/her doctor.

The patient could decide to interrupt the medical relation with his/her doctor at any time without requiring any condition to do so. Thus, because the doctor-patient contract is concluded in the patient's interest and it is patient who chooses the doctor, makes it possible for the patient to dispense of the doctor's attributes when they no longer meet with his expectations (13). The medical liability in case of the interruption of medical care at the patient's request will be judged in terms of civil, criminal or disciplinary action, as appropriate.

3. Patient's right to refuse treatment

According to the Law no. 46/2003, the article 13, it is entitled to refuse or to stop a medical intervention, assuming responsibility for this decision in writing. Consequences of refusing or stopping medical documents must be explained to the patient. Decision of refusal can be made only by competent person (6). The physician has the obligation in this case to ensure that the patient's decision is informed, clear, and free, so informing patient must have the same standard as in the case of the Informed Consent, providing as much information about the consequences. Thus, the doctor must understand that the decision of refusal is not just the responsibility of the patient, but also a professional one in case of informing patient not in a properly way, and the patient could not figure out the risks and injuries of a such choice (13).

5. Patient's right to refuse or stop terminal care

According to the Law No. 46/2003, the patient can refuse any medical intervention, provided by recording this in writing, and explaining the consequences deriving thereof, specified in the article 13. Therefore, we understand that the patient can refuse also the terminal care (6). Terminal care means the care provided to a patient when it is no longer possible to improve the fatal prognosis of the disease state and the treatment given near death (16). The article 190 of the Romanian Criminal Code forbids Euthanasia practices in Romania: "The murder committed at the explicit serious, conscious and repeated request of a victim who was suffering from an incurable illness or serious disablement medical attested, causing him permanent and unbearable suffering, shall be punished with imprisonment from 1 to 5 years" (17).

6. Exceptions of the right to self-determination

Incompetent patient

According to the Romanian Civil Code, the article 43 is unable to take a decision a minor under 14 years and those who are declared incapable by court order. For those who do not have the legal capacity, ends legal acts on their behalf their guardian or legal representative, as provided by law (18). Minors may express their consent in the absence of their parents or legal representatives in cases of emergency when parents or representatives can not be contacted and the child has the ability to understand his/her medical condition, and in cases involving issues of sexual and reproductive request, the minor over 16 years could decide by him/herself (19). According to the article 16 of the Law no. 46/2003, where is required the legal representative's consent, patient should be involved in the decision as far as it has the ability of understanding (7).

Surrogate decision. Nominating guardian

According to the Code of Deontology, the article 13, "Where, under the law, a major because of a mental disability illness or a similar reason has not the capacity to consent to an intervention, it can not be done without the consent of his/her representative or without the authorization of authority or a person or agency appointed by law" (20). The patient may be represented by a legal guardian, a representative of the health system, close relatives, in the following order: spouse, son/daughter, parent, grandparent, grandchild, a close friend (14). Persons who decide for the patient must be informed of the medical act, consequences and its benefits, alternatives and risks.

According to the article 17 of the Law No. 46/2003, if the representative refuses to give consent and the physician determines that the patient needs assistance concerned, the decision will denied to an arbitration panel specialist (7).

FINAL CONSIDERATIONS

In this paper we tried to acquaint all those working in the medical field on the national and international legal context on patient's right to autonomy, including the right to refuse medical treatment. Analysing the legislation we have seen that the principle of patient autonomy is the foundation for both the patient act of consenting to treatment proposed by his doctor, but also to refuse the proposed treatments. However, the acceptance of treatment is much better regulated in legal terms, than the procedure of refusal of treatments. On refusal, the legislation merely says that it must be in writing, without indicating any specifications that these forms must contain, unlike the Consent Forms, where are

indicated marks on what the patient needs to be informed. Our suggestion is to respect the principle of symmetry; so the Refusal Forms should contain the same elements as the Informed Consent. This is supported by the existence of refusal forms already present in medical practice of some countries, like USA or UK.

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