MALPRACTICE AND CIVIL LIABILITY OF THE HEALTHCARE PROFESSIONALS

Cristian-Răzvan CERCEL[*]

Abstract

The issue of the medical malpractice and the liability of the healthcare professionals is more current than ever, given that the medical activity has been put to the test in the context of the COVID-19 pandemic. Thus, taking into account that the treatment and the medical interventions are exercised directly on the patient, it is necessary to establish the type of liability of the healthcare professionals and whether there are certain limits of the liability for the application of innovative treatment or whether, on the contrary, the application of other treatment schemes than those approved by the international medical forums is likely to attracts the liability of the healthcare professionals.

At the same time, this paper aims to present the national legal framework that defines the essential requirements and limits of liability of the healthcare professionals. At the same time, in relation to the case law and doctrine, this paper will seek to establish the main obligations of the healthcare professionals to patients and the nature of these obligations.

In the end, the opinions expressed over time in the doctrine regarding the basis of liability of the healthcare professionals, whether it is a contractual liability or a non-contractual liability, or a special liability, are presented comparatively.

Keywords: *malpractice, non-contractual civil liability, healthcare professionals, harm, health unit.*

1. Introduction

The medical law, in a general sense, can be defined as a branch of the law consisting of legal rules of domestic, European and international law, which regulated the patrimonial or non-patrimonial social relations that are established between the subjects of medical law, usually between the healthcare professionals (doctor, pharmacist, dentist etc.) or public or private health units and patients.

In the doctrine[32], the medical law has been defined as: 'discipline of thinking between medicine and law, supports the realisation of the right to health of the human, based on the fact that the human being is intangible, and the respect for life goes to the respect for death. The medical law becomes a meeting place for the ideal legal, moral or technical rules, with the concrete medical realities'. The work of the doctor involves the protection of the patient's life, while respecting their rights, especially regarding their dignity. Thus, there was a need to enact rules to protect the patient for situations in which the healthcare professionals or the health units, due to a professional error committed in the exercise of the medical act, cause harm to the patient.

One of the most controversial issues, widely debated, both in doctrine and in national or French case law is related to the legal nature of the medical liability.

Many authors consider that this is a contractual liability, others that it is about a non-contractual eminent liability, and other others consider that we may be close to a contractual or non-contractual civil liability, depending on the contractual circumstances of the case.

In any case, as a rule, the legal relationship between doctor and patient is governed by the principle of *intuitu personae*, because the patient has the right to freely choose their doctor, but also the health unit in which to be cared for.

Last but not least, a special importance is also represented by the liability of the health units for the acts of the healthcare professionals, based most of the times on the liability of the principal for the act of the agent.

For starters, the main applicable national legal provisions will be analysed, and then the issues related to malpractice and medical liability will be presented in detail.

2. Legislation applicable to the medical legal relationship

2.1. National legal framework

The domestic legislation related to the medical law has been codified from the level of the Romanian Constitution. The right to health protection is guaranteed by the Constitution, and according to Art. 34 of the fundamental law *the State is obliged to take measures to ensure hygiene and public health, and the organisation of the health care and social insurance system for illness, accidents, maternity and recovery, control of medical professions and paramedical activities are established by law*.

Then, by Law No. 95/2006 *on the reform in health care*[33] ('***Law 95/2006***') a title that is distinct from the civil liability is enshrined, namely Title XVI, entitled '*Civil liability of the healthcare professionals*

[*] PhD Candidate, Faculty of Law „Nicolae Titulescu" University of Bucharest (e-mail: ccristianrazvan@gmail.com).

[32] A.T. Moldovan, *Dreptul medical – ramură distinctă de drept*, in '*Dreptul*' nr. 7/2006, p. 139.

[33] Published in the Official Gazette of Romania No. 372 of 28th April 2006 with the subsequent amendments and supplements.

and providers of medical, sanitary and pharmaceutical products and services'.

At the same time, another normative act of special importance is represented by Law No. 46/2003[34] *on the right of the patients* ('***Law 46/2003***'). Law 46/2003 is considered '*the central pillar of the legal construction on professional malpractice, a true axiological summum of the noblest ideals that guide the activity of every practitioner in the medical field*[35]'.

At the level of the common law, the Civil Code provides in Art. 1357-1371, the civil liability for one's own action, and in Art. 1373, the liability of the principal for the act of the agent, for those situations in which the liability of health unit for the action of the employed health care professional may be involved.

2.2. The legal relationship of medical law

Like any other legal relationship, the medical legal relationship includes the three structural elements: content, object and subject. The structural elements of the medical legal relationship represent certain particularities depending on the applicable legal rule; criminal, administrative or civil.[36] Given the research material of this paper, the rules of civil law will be considered below.

2.2.1. General aspects

The medical legal relationship is a social, volitional legal relationship that is established between persons who have a special quality and to whom the law imposes a certain conduct, without which the legal relationship could not exist.

'*The main objective of the relationship between doctor and patient is to provide medical care, perform interventions or treatment appropriate to the established diagnosis, which involves a high level of professional and scientific trust, patience, discretion, but also respect for their rights to information, security, confidentiality*'[37].

2.2.2. The content of the medical legal relationship

In general terms, the content of the civil legal relationship is given by all the subjective civil rights and civil obligations that the parties to that legal relationship have[38]. Thus, the medical legal relationship also includes all the rights and obligations that the parties to the legal relationship have or are held, regardless of whether or not they arise from the legal rules of the domestic or international medical law.

For example, the main rights of the patients are contained in Law No. 46.2003. We will present below, by way of example, a number of the rights and obligations of the patients and the healthcare professionals.

Rights of patients: the right to medical information, the right to receive the best quality medical care, without any discrimination, the right to confidentiality of information etc.

Obligations of patients: the obligation to inform correctly and completely the healthcare professionals about the symptoms or disease, the obligation to inform the healthcare professionals about any changes in connection with the disease for which treatment is offered, the obligation to follow exactly the doctor's recommendations, the obligation to respect the dignity of the healthcare professionals, the obligation to pay the contributions to the health insurance fund etc.

Rights of healthcare professionals: the right to exercise the professional freely and independently, the right to refuse a patient, when the law allows it, the right to establish medical treatment according to his/her knowledge, the right to remuneration etc.

Obligations of healthcare professionals: the obligations to maintain professional secrecy, the obligation to respect the dignity of the patient, the obligation to inform the patient about the real health status and on the risks of the prescribed treatment etc.

2.2.3. The object of the medical legal relationship

The object of the medical legal relationship is the conduct of the parties, i.e. the concrete action or inaction to which the parties are entitled or which they must comply with.

2.2.4. The subjects of the medical legal relationship

One of the subjects of the medical legal relationship is the **patient**. According to Art. 1 letter a) of Law 46/2003, the patient is a healthy or sick person who uses health services.

On the other hand, the subjects of the medical relationship are also the individuals who provide medical services, respectively the doctor, the dentist, the pharmacist, the nurse, the midwife, etc. or legal persons directly or connectedly involved in the provision of medical care and services, such as public or private health units, as providers of medical services, manufacturers of medical equipment, medicinal substances and medical materials etc.

2.3. Obligation of means or obligation of result

The legal relationship between the doctor and his/her patient is the classical example of obligations of means. The obligations of means are the obligations which consist in the duty of the provider to make every effort to achieve a certain result, without committing to the intended result in itself.[39].

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[34] Published in the Official Gazette of Romania No. 51 of 29th January 2003 with the subsequent amendments and supplements.
[35] L.B. Luntraru, *Răspunderea civilă pentru malpraxisul profesional*, Ed. Universul Juridic, Bucharest, 2018, p. 164.
[36] A. Sas, *Răspunderea civilă medicală – Răspunderea civilă delictuală*, Fiat Iustitia nr. 2/2009, p. 79.
[37] L.B. Luntraru, *op. cit.*, p. 165.
[38] G. Boroi, C.A. Anghelescu, *Drept civil. Parte generală. Ediția a II-a revizuită și adăugită*. Ed. Hamangiu, Bucharest, 2012, p. 53.
[39] G. Boroi, C.A. Anghelescu, *op. cit.*, p. 70.

If has also been shown that '*starting from the adage Non est in medico semper relentur ut aeger (no doctor can always guarantee that his/her patient will recover), the qualification of the doctor's obligations as obligations of means appears to be obvious*'[40].

Specifically, the healing of the patient does not depend exclusively on the science, skill or diligence of the doctor, being often determined by factors and circumstances that are not covered by the actions of the healthcare professionals, such as: insufficient evolution of medicine to establish the exact diagnosis, the medication assigned to the patient does not produce the expected result.

However, both in practice and in doctrine, the opinion was outlined in the sense of the need to divide the obligations of the doctor into obligations of means and obligations of result. Thus, it is estimated that '*whenever the doctor assumes a certain provision, the result of which does not depend on the relativity of the medical act, then the generic obligation of care will be the result*'.[41] The examples are: the obligation to make a dental prosthesis or orthosis, the obligation of the doctor to draw up the consultation sheet/record of the patient, as well as the obligation to make a test: blood, urine, etc. In such hypotheses where the desired result is obtained without risk, without the intervention of random external factors, the expected result is the exclusive responsibility of the debtor, therefore, of the healthcare professionals.

Regarding two of the obligations of the doctor, the doctrine outlined opposing opinions, meaning the obligation of security and the obligation to inform the patient.

On the other hand, some authors considered that the obligation of information and the obligation of security are predominantly obligations of result[42], and on the other hand, other authors considered that they are predominantly obligations of means[43].

2.3.1. Obligation of security

The content of this obligation includes the duty, to preserve during the medical act the physical and mental integrity of the patient, by his/her doctor.

Although the nature of this obligation has long been debated, especially in the French doctrine, in the sense that there have been authors who have stated that it is not a real obligation, but a component of the obligation to care for the patient, as far as we are concerned, we consider that the obligation of security is an autonomous obligation, but ancillary to the obligation to care for the patient.

Without initiating the issue of the explicit or not reference of this obligation, we appreciate that it cannot have as source the Government Ordinance No. 21/1992 *on consumer protection*[44] ('***GO 21/1992***') unless we admit that the legal relationship between doctor and patient is contractual, and the patient is a consumer, and the doctor is a service provider.

However, we appreciate that we cannot equate the medical contract with a real consumer contract.

As mentioned above, the obligation of security is ancillary to the obligation to care for the patient, and by virtue of the principle *accesorium sequitur principallem*, we consider that the obligation of security is in principle and obligation of means. Although the obligation is performed by a professional, it cannot be qualified as an obligation of result, because random factors in the medical activity must be taken into account, which can aggravate the health status of the patient. Consequently, the fault of the professional in fulfilling the obligation must be proven, because the healthcare professionals cannot guarantee the preservation of the physical and mental integrity of the patient. In fact, this solution is also natural, because a random factor is related to the behaviour of the patient that can contribute to the unfavourable evolution of his/her health status.

Finally, certain nuances must be admitted in relation to those set out above. The obligation of security may acquire the valance of an obligation of result when the healthcare professionals show recklessness, incompetence, inability or ignorance, by disregarding risks unanimously known and accepted at the level of the medical community or at the current level of scientific research.

At the same time, even in case of improper use of medical devices, sanitary materials or medical products, it can be noted that the obligation of security is a result.

2.3.2. Obligation of information

Perhaps one of the most important obligations of the healthcare professionals, especially of the doctor, is the obligation of information. In the literature, the obligation of information is perceived as an obligation inherent in the exercise of a profession, therefore a professional one.

The healthcare professionals must inform the patient exhaustively, in relation to the level of knowledge existing at that time, about the various investigations, treatments or preventive actions to be carried out. At the same time, the healthcare professionals have the role, based on this obligation, to

[40] L.B. Luntraru, *op. cit.*, p. 171.

[41] F.I. Mangu, *Răspunderea civilă a personalului medical și al furnizorilor de produse și servicii medicale, sănătate și farmaceutice. Teză de doctorat*. *Rezumat*. Universitatea de Vest din Timișoara. Facultatea de Drept și Științe administrative. Timișoara. 2010, p. 5.

[42] V. L.R., *Discuții privitoare la răspunderea civilă pentru încălcarea obligației medicale de informare a pacientului*, in Dreptul nr. 2/2013, p. 103-123; L.R. Boilă, L.B. Luntraru, *Repere teoretice și practice privind definirea obligației civile de securitate. op. cit*., p. 82-103, in L. Pop, I.F. Popa, S.I. Vidu, *Curs de drept civil. Obligații*. Ed. Universul Juridic, Bucharest, 2015, p. 403.

[43] F.I. Mangu, *op. cit.*, p. 6.

[44] Published in the Official Gazette of Romania No. 212 of 28th August 1992 with the subsequent amendments and supplements and republished.

inform the patient about the urgency of an intervention, as well as the consequences or risks to which they are exposed in case of a refusal.

Of course, the obligation of information will be made in relation to the known or objectively predictable risks, assumed by a certain medical procedure, and not on the fortuitous risk, i.e. accident, unpredictable at the date of information and unknown by the doctor[45].

Moreover, this obligation is not limited to the initial time of the consultation, for example, but must be fulfilled throughout the relationship between doctor and patient. In other words, the healthcare professionals must keep the patient informed of the evolution of their health status throughout the monitoring and inform them of any changes that occur.

The obligation to inform the patient in order to obtain the consent for performing certain medical acts is stipulated in Law 95/2006. However, simply signing the consent is not enough to consider that the obligation has been fulfilled.

The healthcare professionals must ensure that the patient understand the information provided. Therefore, according to Art. 660 para. (2) of Law 95/2006, '*the doctor, the dentist, the nurse/midwife are obliged to present to the patient the information at a scientifically reasonable level for their understanding*'. Specifically, the information must be correct, clear and appropriate to the level of knowledge of the patient.

In principle, it has been expressed in the French doctrine the opinion that the obligation to inform is an obligation of means, the healthcare professionals having the obligation to make every effort to inform the patient about the risks of the medical procedures to be applied, in which case the doctor, for example, will be absolved of liability.

As far as we are concerned, we appreciate that the result of which the doctor is bound to is to obtain the informed consent of the patient, given in full knowledge of the facts.

This, the liability of the healthcare professionals will be engaged in the situation where the patient has not been informed in any form in advance, as well as in the situation where the information was not correct, clear and adequate.

In the event of a dispute, the healthcare professional or health unit must prove that the information has been provided correctly. The proof can be made by any means of proof.[46] Therefore, the obligation of information is a relative obligation of result.

Usually, the non-fulfilment of this obligation leads to a specific moral harm, which is based on the inadequate psychological training of the patient. This can be combined with the harm consisting in the loss of a chance to avoid the harm resulting from the realisation of the risk of the medical act[47].

3. Malpractice

According to Art. 653 paragraph 1 letter b) of Law 95/2006, the act of malpractice is 'the professional error committed in the exercise of the medical or medical and pharmaceutical act, generating harm to the patient, involving the civil liability of the healthcare professionals and the provider of medical, sanitary and pharmaceutical products and services'.

The fault is the one that characterises, from the point of view of form, the guilt with which the medical malpractice is objectified, the legislator speaking about professional error, negligence or recklessness.

The error can be committed either by action or omission, and the burden of proof lies with the harmed party. The simple error without patrimonial or non-patrimonial consequences cannot be classified as an act of malpractice. For example, the mere misdiagnosis is not in itself an error, but if this leads to improper treatment of failure to perform surgery, then the error may be an act of malpractice.

4. The legal nature of medical liability

When the legal conditions are met, the liability of the doctor, dentist, pharmacist, nurse and midwife may be jointly and severally, if applicable, with what of the health unit in which they operate, being applicable the provisions of the Civil Code regarding the liability of the principal for the act of the agent.

The issue of the classification of civil liability for medical malpractice has been and is discussed in direct relation to the opinions regarding the nature of the legal relationship between the patient and the healthcare professionals and sometimes between the patient and the health unit where they work.

Several opinions have emerged in the literature. In a first opinion, it was considered that the civil liability of the healthcare professionals can be either contractual or non-contractual, depending on the health network (public or private) where they work. In a second opinion, it was shown that the medical civil liability is always a non-contractual liability, and in the end there were authors who considered, without distinguishing between the public or private health unit[48], that the liability is strictly contractual[49].

4.1. Contractual liability

As we have shown in the previous paragraphs, in classifying the legal nature of the medical liability as a

[45] F.I. Mangu, *op. cit.*, p. 7.
[46] L.B. Luntraru, *op.cit.*, p. 185.
[47] *Ibidem.*
[48] I. Anghel, F. Deak, M. Popa, *Răspunderea civilă*, Ed. Științifică, Bucharest, 1970.
[49] V. Fl. I. *Malpraxisul medical. Răspunderea civilă medicală*, Wolters Kluwer, Bucharest, 2010, p. 116-245; I. Turcu, *Dreptul sănătății. Frontul comun al medicului și juristului*, Wolters Kluwer, Bucharest, 2010, p. 158, in L. Pop, I.F. Popa, S.I. Vidu, *op. cit.*, p. 400.

contractual liability, some authors make the distinction according to whether the healthcare professionals is part of the public or private health network.[50]. Thus, it was unjustifiably considered that, in the case of private forms of practicing medicine, the liability is a contractual one, and in the rest of the cases, it is a question of non-contractual liability.

On the other hand, there were authors who considered that '*the rule on the provision of healthcare/medical care is, from a legal point of view, the contract of healthcare/medical care concluded between doctor, dentist and patient, regardless of the system in which the doctor carries out his/her activity, publicly or privately*'[51]. Consequently, it is considered that the healthcare professionals will be held liable according to the rules of the contractual civil liability in any situation.

In support of this opinion, it was appreciated that the legal obligation to provide medical care or specialised care is conditioned by the meeting of the agreement of the patient with that of the competent healthcare professional, and thus the healthcare contract is established.

However, two exceptions are known within this concept, when the liability of the healthcare professionals towards the harmed patient will be of a non-contractual nature. The first hypothesis concerns the situation of the patient who is in a state of clinical emergency, being unconscious, therefore unable to express his/her consent, and the second, when the patient does not have the necessary discernment to express a valid consent.

We cannot agree with this opinion, because the choice of the doctor and the expression of informed consent is only an individual act of acceptance of the medical decision. Thus, the obligations of the healthcare professionals are not contractual obligations, but legal obligations expressly and imperatively provided by law.

At the same time, we appreciate that the liability could not be a contractual one, because the violated obligation is a legal obligation, of a general nature, which belongs to all persons in the health system and not only to a certain doctor or persons. Moreover, the obligations of the healthcare professionals are imperative from which they cannot be derogated, or in the case of contractual civil liability, the non-liability clauses as allowed, as a rule. Thus, it would be difficult to conceive that these non-liability clauses would be allowed in terms of the relationship between doctor and patient. The rules established by law in the field of medical law protect a general interest to protect the entire population from those diseases that could pose a danger to public health.

4.2. Non-contractual liability

It has traditionally been held in doctrine and case law, rightly, that the relationship between the healthcare professionals and the patient is an extra-contractual relationship, and in case of non-fulfilment of obligations by the healthcare professionals, the non-contractual liability will be engaged. This conception is based on the argument that life, health, physical and mental integrity cannot be the subject of a convention, being null and void.

4.3. Professional liability

Last but not least, the idea that the medical civil liability is neither non-contractual nor contractual, but a specific professional liability of the healthcare professionals, which intervenes for harms caused by a professional error, has emerged relatively recently[52].

The opinion is also shared by other authors[53] who consider that the liability regime for medical malpractice transcends the classic distinction between non-contractual liability and contractual liability, because we are witnessing a process of decontractualisation of these obligations, being, therefore, a liability of the professionals called medical civil liability.

5. Exemptions from liability

Finally, regardless of the type of liability (contractual, non-contractual, professional), the provisions of Art. 654 paragraph 2 letters a) and b) exhaustively provide for the exonerating causes of liability:

- when the working conditions in which the healthcare professionals carry out their activity are non-compliant, respectively if they have had an insufficient endowment with the diagnostic and treatment equipment or a nosocomial infection has occurred;
- random factors that have led to complications and risks in the techniques used or adverse effects;
- hidden defects of the sanitary materials, medical equipment and devices, medical and sanitary substances used;
- when the healthcare professionals act in good faith in emergency situations, as long as the competencies granted are respected.

6. Conclusions

In the current context, the medical liability is still a topical issue. The national and international doctrine and case law is constantly evolving, bringing new arguments to support the nature of the medical legal relationship. As we have shown in detail in this paper,

[50] V.I. Albu, *Răspunderea civilă contractuală pentru prejudiciile nepatrimoniale (daunele morale)*, Dreptul nr. 8/1992, p. 32; I.F. Popa, Răspunderea civilă medicală, in Dreptul nr. 1/2003, p. 46, in *ibidem*.

[51] F.I. Mangu, *op. cit.*, p. 3.

[52] L.R. Boilă, *Răspunderea civilă delictuală subiectivă*, Ed. C.H. Beck, Bucharest, 2009, p. 326.

[53] L. Pop. in L. Pop, I.F. Popa, S.I. Vidu, *op. cit.*, p. 403.

we appreciate that the legal relationships between patients and healthcare professionals are extra-contractual relationships resulting from the law and not from a convention concluded between the subjects of the legal relationship.

Moreover, the national case law leans towards the same solution, taking into account the regulations in force.

The acts of medical malpractice are among the most diverse, and the settlement of disputes aimed at awarding damages resulting from these medical errors is a real challenge for the courts. This is also due to the constant evolution of medicine.

Therefore, we are convinced that both the current regulations at national and international level, as well as the regulations that will appear, will lead to the creation of medical law as a distinct branch of law.

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