

# MEDICAL MALPRACTICE. THE MALPRACTICE INSURANCE

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## Abstract

*Increasingly, complaints about medical malpractice occur extreme situations such as the death of the person or the occurrence of irreparable injuries. Professional misconduct in the exercise of the medical or medical-pharmaceutical act generating harm to the patient implies the civil liability of medical personnel and the provider of medical, sanitary and pharmaceutical products and services. Law no. 95/2006 on the health reform stipulates the obligation of the medical staff to conclude a malpractice insurance for the cases of professional civil liability for the damages created by the medical act, the indemnities being the responsibility of the insurer, within the limits of the liability established by the insurance policy.*

**Keywords:** *medical, malpraxis, insurance, liability, sanction*

## 1. Introduction

From the etymological point of view, the word malpraxis defines an inappropriate practice, being an internationalized, self-governing word, used only in the medical field, and currently spreading to other professions such as lawyer, notary public, Bailiff, etc. Also included in the explanatory dictionary of the Romanian language, it defines malpractice as an "improper or negligent treatment applied by a doctor to a patient, which causes him harm of any nature in relation to the degree of impairment of physical and mental capacity." In the Romanian legal system, any person has the duty to observe the rules of conduct which the law or custom of the place requires, and not to interfere with his actions or inactions, the rights or legitimate interests of others. The one who, having discernment violates this duty, is liable for all the damages caused, being obliged to repair them fully. At the same time, the person who contracts obligations is held to execute them, otherwise being responsible for the damage caused to the other party, being obliged to repair it. Specific malpractice is even the existence of rules of conduct imposed by the profession and the professional body, which establish competences and attributions in the field, rules that are violated by the professional, attracting his responsibility.

Professional misconduct in the exercise of the medical or medical-pharmaceutical act generates harm to the patient, involving the responsibility of the doctor or the medical staff. Like civil liability, the malpractice also seeks to repair the damage caused by committing an illicit act in a pre-existing legal relationship between a professional and a patient. Thus, medical malpractice is interested in determining who is to respond to the action or inaction, establishing the extent of the damage created and the limits to which the responsible person can answer.

Title XVI of Law no. 95/2006 on Health Reform establishes the extent of the civil liability of medical personnel, as well as the procedure for determining the cases of professional liability. At the same time, the same normative act imposes the duty of those who grant medical assistance, to conclude a malpractice insurance for the cases of professional liability for damages caused by the medical act.

## 2. Medical practice

The legal notion of medical malpractice is defined by art. 653 par. (1) letter b) of the Law no. 95/2006 on the health reform as being professional misconduct in the exercise of the medical or medicopharmaceutical act generating harm to the patient, involving the civil liability of medical personnel and the supplier of medical, sanitary and pharmaceutical products and services. Within the same normative act, medical staff is the doctor, dentist, pharmacist, nurse and midwife who provides medical services. Starting from this definition, we note that engaging civil liability in malpractice-specific conditions occurs when the individual violates a rule of professional conduct. At the same time, one of the conditions of malpractice is that there is a legal relationship of the professional nature (doctor-patient) between the victim of the injury and the victim<sup>1</sup>.

However, it is well known that the basis of civil liability is either the law or the parties' contract. Regarding the subject of this article, according to the legal provisions (art.653 corroborated with art.660 et seq. From Law no 95/2006), we may consider that the basis of the doctor's responsibility for failure or poor fulfillment of the professional obligations has its source both in Law, but also in the medical agreement (patient informed consent).

However, the informed patient's consent implies that, prior to being subjected to any method of prevention, diagnosis and treatment with potential for

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<sup>1</sup> Dan Cimpoieru, *The malpractice*, Ed. C.H.Beck, Bucharest 2013 p. 27.

patient risk, the physician has the duty to explain in reasonable terms the patient's ability to understand, will be subjected. In turn, the patient gives his written consent for the medical procedures.

In fact, written consent is only a guarantee that the patient has agreed to perform a particular medical procedure, without totally or partially exonerating him from a responsible physician in case of a professional error<sup>2</sup>.

Thus, we can not consider the patient's informed consent as a genuine contract, as the doctor's obligations are not established. The main consequence of this circumstance is that, in the case of malpractice, we can not speak of a contractual civil liability, but exclusively of civil tort liability, the doctor's obligations stemming from the law.

Medical civil liability is always a criminal liability because life, health, physical or mental integrity can not be the subject of a convention, and if such legal acts were concluded, they should be considered null and void under Art. 1229 Civil Code, according to which, "only goods that are in the civil circuit may be the subject of contractual provision"<sup>3</sup>.

As a form of tort law, malpractice, in most cases, is found in the form of civil liability for its own deed, as a form of tortious civil liability. Even though the law also governs other forms of tort / delict liability, liability for other person's deeds and damage caused by things, these are atypical for malpractice.

### 2.1. Conditions of Liability for Own Deed

The provisions of art. 1357 paragraph (1) of the Civil Code state that "the one who causes another to suffer an offense by an offense committed with guilt is obliged to fix it." Therefore, the general conditions regarding tort liability in the sense that there must be an unlawful deed, injury, causality and guilt must be met. Liability for own deed is the principal area of liability based on the fault of the perpetrator, the fault not presumed, but must be proven by the victim.

As far as the professional error (illicit deed) is concerned, it has not been given a legal definition, but the legislator<sup>4</sup> has exemplified the forms of this error. Medical staff is civilian responsible for:

- professional error;
- insufficient medical knowledge in the exercise of the profession;
- preservation of legal regulations on confidentiality, informed consent and the obligation to provide medical assistance;
- depending limits of competence, except in the case of emergency where no medical personnel with the necessary competence is available.

Nonetheless, the lawyer also provided for the medical staff not to be liable for damages and damages in the exercise of the profession, namely when these damages:

- a) is due to working conditions, insufficient equipment with diagnostic and treatment equipment, nosocomial infections, adverse effects, complications and generally accepted risks of investigation and treatment methods, hidden vices of sanitary materials, medical equipment and devices, sanitary equipment used;
- b) acting in good faith in emergency situations, respecting the competence granted<sup>5</sup>

In the provision of health care and / or health care, medical staff is required to apply therapeutic standards established by nationally approved practice guides or, failing that, standards recognized by the medical community of that specialty, which What could enable the circumstance of the illicit medical offense.

Injury, as an essential element of medical civil liability, consists in the negative result suffered by the patient as a user of medical services as a result of the illicit act committed by the physical or legal person providing medical services<sup>6</sup>.

According to art. 1385 Civil Code, the damage shall be fully rectified, unless otherwise provided by law. Compensation will also be granted for future damage if its production is unquestionable. Compensation must include the loss suffered by the injured person, the gain he would have been able to make and which he was deprived of under normal conditions, and the expenses he has incurred for the avoidance or limitation of the damage. If the illicit act also determined the loss of the chance to gain an advantage, the reparation will be proportional to the probability of obtaining the advantage, taking into account the circumstances and the victim's concrete situation.

In the case of injury to a person's bodily integrity or health, the compensation must include, as the case may be, the gain from the work that the injured person was deprived of or prevented from acquiring through the loss or reduction of his / her work capacity. In addition, the indemnity must cover the costs of medical care and, if applicable, the expenses related to the increased life needs of the injured person, as well as any other material damage<sup>7</sup>.

If the person who suffered harm to bodily integrity or health is a minor, the established disparity will be due from the date when the minor would normally have completed his / her professional training. . Until that date, if the minor had a win at the time of

<sup>2</sup> Dan Cimpoieru, *The malpractice*, Ed. C.H.Beck, Bucharest 2013 p. 86.

<sup>3</sup> Roxana Maria Calin, *Malpraxis - Liability of medical staff and healthcare provider. Judicial Practice - 2nd Edition*, Ed. Hamangiu, Bucharest, 2016., p. 87.

<sup>4</sup> Art. 653 par. (2) of Law no. 95/2006 on health reform with subsequent amendments and completions.

<sup>5</sup> Art. 654 par. (2) of Law no. 95/2006 on health reform with subsequent amendments and completions.

<sup>6</sup> Roxana Maria Calin, *Malpraxis - Liability of medical staff and healthcare provider. Judicial Practice - 2nd Edition*, Ed. Hamangiu, Bucharest, 2016, p. 91.

<sup>7</sup> Art. 1387 Civil code.

the injury, the compensation would be determined on the basis of his lost earnings, and if he did not have a win, he shall be determined according to the provisions of art. 1388 Civil Code, which applies accordingly<sup>8</sup>.

The damage may be of a patrimonial (economic) or non-patrimonial (moral) nature. Even if the damage is not susceptible to a pecuniary assessment, the compensation to be awarded for this damage will have a patrimonial character.

As regards the moral prejudice, as its difficult assessment, the courts, when granting moral damages, do not operate with predetermined evaluation criteria, but proceed to an appreciation subjective of the particular circumstances of the case, namely the physical and psychological sufferings suffered by the victim<sup>9</sup>, as well as the adverse consequences that the event under consideration had on the particular life, taking into account the evidence to be administered.<sup>10</sup> Thus, the judge is placed in the situation of estimating such damages, on the basis of estimated criteria that can highlight the limits of appreciation of the amount of the indemnities.

It is necessary that there is a causal relationship between the illicit act and the damage, namely the damage caused as a consequence of the illicit deed. The causality report includes both the facts that are the necessary and direct cause, as well as the facts that have made the causal action possible, or have ensured or aggravated its harmful effects. In order to establish the causal relationship between the illicit medical act and the damage, it is necessary to establish, on a scientific basis, all the correlations between the facts and the circumstances<sup>11</sup>.

Article 1358 The Civil Code differentiates the particular situations of appraisal of guilt. Thus, in assessing the guilt, account will be taken of the circumstances in which the damage occurred, which is foreign to the person of the perpetrator, and, if so, of the fact that the damage was created by a professional in the operation of an enterprise.

Since medical liability, as a civil liability, is based on the classic guilt (fault), professional misconduct could be defined as a form of guilt where the physician did not foresee the outcome of his deeds, although he could have foreseen it, or predicted the results of his actions, but he considered it to be easy that they would not appear.

Medical professional misconduct consists of non-observance of the rules regarding the exercise of the medical profession by failing to adhere to or deviations from the usual rules recommended and recognized in the practice of this profession, resulting from negligence, lack of attention or non-observance of specific methods and procedures.

Any form of professional misconduct can be identified by reference to the following:

- *culpa in adendo* – adherence to professional misconduct, imprudence, incomprehension, non-indifference to the requirements of the profession or the risks to which a person is exposed, the inappropriate use of working conditions, or an ease in medical activity that calls for special attention and caution;
- *culpa in eligendo* – consists in the wrong choice of technical procedures, in a delegation to an inappropriate person of obligations or in the delegation of their own obligations to others;
- *culpa in omitendo* – when the patient loses the chance of healing or survival due to the failure to carry out necessary gestures;
- *culpa in vigilando* – which resides in the breach of a duty of confraternity on a request for the request and the obligation to answer it, the failure to ask for help, the failure to inform the patient about the fate of the patient.<sup>12</sup>

When establishing the guilt, the objective criterion of average diligence will be taken into account. If the physician's obligation to treat the patient is a means of diligence, caution, the doctor - without guaranteeing the outcome (healing), assumes the obligation to have the necessary conduct and to apply the most suitable medical remedies for the purpose of patient's recovery<sup>13</sup>. The result has a random nature, being influenced by the specific reactivity of the patient, the particularities of the disease, false or incomplete information obtained from the patient, or the limited technical and scientific resources available at the time of treatment<sup>14</sup>.

## 2.2. Legal Liability of Medical Service, Sanitary Materials, Appliances, Medical Devices and Medicines Providers.

Along with the civil liability of medical personnel for the professional misconduct in the exercise of medical or pharmaceutical medicine, Law no. 95/2006 also regulates the civil liability of the providers of

<sup>8</sup> Art. 1389 Civil code.

<sup>9</sup> In the case of the trial, the applicant suffered psychological trauma as a result of the fetus' death, but also because she had to look for answers for 5 years, as all those involved constantly refused to offer it. The court held that, in the context of the circumstances of the case and taking into account the actual suffering of the applicant, the amount of 200,000 lei claimed for moral damages is a fair satisfaction – *Jud.Sect.1 Bucuresti, sent.civ. nr. 11541/ 26.06.2013*.

<sup>10</sup> Roxana Maria Calin, *Malpraxis - Liability of medical staff and healthcare provider. Judicial Practice - 2nd Edition*, Ed. Hamangiu, Bucharest, 2016, p. 97.

<sup>11</sup> Regarding the causal link between the illicit act and the injury, the court noted that the doctors' inaction triggered, favored and did not in any way prevent the constitution of the causal chain that resulted in the fetal death of the fetus and the danger of the mother. The guilt of the doctors constantly in the form of omission, manifested in some inactions by not performing some necessary actions, namely not knowing the correct diagnosis and not taking the necessary treatment measure - *Jud.Sect.1 Bucuresti, sent.civ. nr. 11541/ 26.06.2013*.

<sup>12</sup> Dan Cimpoieru, *The malpractice*, Ed. C.H.Beck, Bucharest 2013 p. 90.

<sup>13</sup> Gabriel Adrian Nasui, *Medical malpractice*, Universul Juridic, Bucharest 2016, p. 103.

<sup>14</sup> Gabriel Adrian Nasui, *Medical malpractice*, Universul Juridic, Bucharest 2016, p. 103.

medical services, sanitary materials, appliances, medical devices and medicaments for damages to the patient.

Thus, healthcare providers are responsible for their own deed, for the deed of another person, but also for the damage caused by things.

Regarding the responsibility for their own deed, the public or private sanitary units as providers of medical services are liable civilly according to the law for the damages caused by the prevention, diagnosis or treatment activity, if they are the consequence of:<sup>15</sup>

- a) nosocomial infections, unless it is proven to be an external cause that could not be controlled by the institution;
- b) known defects of abusively used devices and medical devices without being repaired;
- c) the use of sanitary materials, medical devices, medicinal and sanitary substances, after the expiry of the warranty period or the term of their validity, as the case may be;
- d) acceptance of medical equipment and devices, sanitary materials, medicinal and sanitary substances from suppliers, without the insurance provided by the law, as well as the subcontracting of medical or non-medical services from providers without civil liability insurance in the medical field.

Public or private healthcare providers providing healthcare services are civilly liable for damages caused, directly or indirectly, to patients by failure to comply with the internal regulations of the sanitary unit.

Besides the responsibility for their own deed, the providers of medical services - public or private sanitary units - are also responsible for the deed of another, respectively for the deed of medical personnel.

Art. 655 par. (2) of Law no. 95/2006 stipulates that the medical units are liable under civil law for the damages caused by the hired medical personnel, in solidarity with him.

Therefore, we are in the presence of the commissioner's responsibility for the deed regulated by art. 1373 Civil Code.

With regard to liability for damage caused by things, public or private healthcare providers, and medical device and medical device manufacturers and healthcare manufacturers are responsible under civil law for harm to patients in the prevention, diagnosis and Treatment, generated directly or indirectly by hidden defects of medical equipment and devices, medicinal substances and sanitary materials during the warranty / period of validity, in accordance with the legislation in force.

### **2.3. The procedure to be followed in order to establish malpractice cases**

**2.3.1.** Establishing cases of malpractice has two procedures, an extrajudicial and a judicial procedure.

As regards the out-of-court procedure, as regulated by the Law on Health Reform, the Methodological Norms of Law no. 95/2006 and the Regulation on the organization and functioning of the monitoring committee and the professional competence for the cases of malpractice, approved by Order no. 1343/2006. This is a voluntary procedure, not compulsory.

Thus, the procedure for establishing cases of malpractice does not prevent free access to justice under common law. The optional nature of this procedure is manifested not only by the possibility of the person interested in choosing between the two ways - the extrajudicial and the judicial procedure - but also by his right to leave the special procedure for the determination of the cases of professional civil liability and to address of the court<sup>16</sup>.

The minimum mandatory elements that a referral to the Commission must contain in order to be subject to verification are:

- the first and last name of the person making the referral;
- the quality of the person making the referral;
- the name and surname of the person who considers himself the victim of a malpractice case, if different from the person making the referral;
- the name and surname of the perpetrator of the act of malpractice perceived, committed in the performance of a prevention, diagnosis and treatment activity;
- the date of the act of malpractice;
- the description of the deed and its circumstances;
- the damage caused to the victim;

In the proceedings before the Commission, the interested person will participate, that is, the person or, as the case may be, his legal representative who considers himself the victim of a malpractice committed in the course of a prevention, diagnosis and treatment activity or the deceased's successor As a result of an act of malpractice imputable to a prevention, diagnosis and treatment activity.

Besides the injured person, they have the status of parties to the extrajudicial procedure and the insured person (the person who committed the malpractice act - the medical staff) and the insurer (the insurance company with which the person accused of malpractice has concluded the civil liability insurance contract). Also, there may be medical experts who can be consulted by the Commission in cases of medical malpractice.

Within 3 months of referral, the Commission must take a decision on the case, a decision that will be communicated to all concerned, including the insurer.

If the insurer or any of the parties disagrees with the Commission's decision, it may appeal to the competent court within 15 days from the date of the communication.

<sup>15</sup> Art. 655 of the Law no. 95/2006 on healthcare reform with subsequent amendments and completions.

<sup>16</sup> Dan Cimpoieru, *The malpractice*, Ed. C.H.Beck, Bucharest 2013 p.118.

**2.3.2.** The entitled person may at any time leave the administrative jurisdictional procedure before the Commission and may address the court. In all these cases, the court acts as a court of full jurisdiction, invested with the resolution of an action in tort. At the same time, the court also acts as a judicial review body when verifying, in terms of its soundness and legality, the Commission's decisions.

The competent court to resolve malpractice litigation is, according to art. 687 of the Law no. 95/2006, the court in whose territorial jurisdiction took place the alleged malpractice.

By indicating the court an exclusive competence, both material and territorial, is established.

In the case of a tort action for malpractice, addressed directly to the court, it will not be possible to resolve the case in the absence of a forensic expertise.

Insofar as criminal acts and deontological norms have been violated by the same act in its materiality, legal liability accumulates, both criminal responsibility and tort liability.

Malpractice acts within the medical activity of prevention, diagnosis and treatment are prescribed within 3 years from the occurrence of the injury.

### 3. The malpractice insurance

In all situations, professionals are required by law or by their own body regulations to end malpractice insurance.

Regarding the compulsory insurance of the initiated medical personnel, this was regulated by the law on insurance and reinsurance in Romania but was later introduced in Law no. 95/2006 on health reform.

The malpractice insurance is in fact insurance for civil tort liability, which means that, in addition, civil law regulations will be applied regarding the liability for the offense and the other legal norms with the incidence in the matter<sup>17</sup>.

Ensuring malpractice has an important role in the work of professionals. On the one hand, he assures the professional against the risk of civil liability and, on the other hand, confers on the victim the certainty that his prejudice will be covered to a greater extent even though the author of the damage would be insolvent.

Moreover, ending insurance is also a sine qua non condition for the doctor who is to be employed, being obliged to submit a copy to the employing unit<sup>18</sup>.

Even if the doctor has the obligation to present insurance when concluding the contract of employment, insurance must be maintained throughout medical practice. Moreover, the failure to conclude the medical malpractice insurance or to ensure the legal limit is a disciplinary offense. The jurisprudence also

established that<sup>19</sup> since the Romanian law expressly regulates the provision of malpractice to healthcare personnel as a form of insurance against it, individually concluded, distinct from any form of insurance concluded by the medical institution, it is obvious that the insurance contract concluded between the medical institution and the insurer does not include insurance for malpractice.

At the same time, with regard to professional liability insurance, the legislator<sup>20</sup> provided for the possibility of coexistence of more valid insurance, in which case the indemnities due will be borne in proportion to the amount insured by each insurer.

Regarding the damages, the legal provisions establish that the insurer pays damages for the insured persons who are liable, under the law, to third parties who are found to have been subjected to a medical malpractice act, as well as to the costs of the injured party Through the medical act.

Art.669 par. (1) of Law no. 95/2006 provides that damages are to be paid in respect of amounts which the insured is obliged to pay by way of compensation and legal costs to the person or persons injured by the application of inadequate medical assistance, which may have the effect of including personal injury or death.

Compensation to be granted when healthcare has not been granted, although the status of the person or persons who have applied for or for whom healthcare was required implied this intervention.

The medical malpractice insurance does not cover the damages that the doctor, pharmacist, nurse or midwife who provides healthcare services will incur in the medical act.

For such damages, medical staff will have to cover the risk of accidents and occupational diseases as any other employee<sup>21</sup>.

An important aspect of interest in the provision of medical liability is the place where the risks and damages specific to this form of insurance are incurred.

Involved activity and health care is given in hospital units, but there are cases when given outside these units, does the question arise whether the doctor's responsibility can be drawn in such situations? The answer is affirmative. The responsibility of the medical staff and, implicitly, the liability of the insurer, regardless of the place where the assistance or medical services were provided, may be attracted.

The Law on Health Reform, by the provisions of Art. 668, provides for indemnity to pay regardless of where the care was given. In conclusion, the medical malpractice insurance operates only if the inadequate assistance has been voluntarily granted outside the specially designated areas<sup>22</sup>.

<sup>17</sup> Vasile Nemes, *Medical malpractice insurance* in Romanian Journal of Business Law no. 2/2009, p. 2.

<sup>18</sup> Art. 667 para. (2) of Law no. 95/2006.

<sup>19</sup> Decision no. 2658 of September 24, 2014, rendered in appeal by the Civil Division of the Supreme Court of Justice.

<sup>20</sup> Art. 671 of Law no. 95/2006

<sup>21</sup> Vasile Nemes, *Medical malpractice insurance* in Romanian Journal of Business Law no. 2/2009, p.9.

<sup>22</sup> Vasile Nemes, *Medical malpractice insurance* in Romanian Journal of Business Law no. 2/2009, p.9.

Relevant to medical liability insurance is the quality of the persons to whom the indemnities will be secured.

Thus, the insurer pays the indemnities directly to the injured party, insofar as he was not compensated by the insured. If the insured proves that he has compensated the injured party, the indemnity shall be paid to the insured. In case of death, the indemnities are granted to the successors of the patient who have requested them. As far as the patient's rights successors are concerned, they have to do so in this regard. Moreover, the insurer will not pay compensation *ex officio*, but only at the express request of the patient's successors.

The settlement and award of damages usually takes place amicably, when the insured's liability is clearly established.

The certainty of the insured's liability may result from a court decision or may be set by the Monitoring and Professional Competence Commission for malpractice cases.

#### 4. Conclusions

The responsibility of the holders of liberal professions is an instrument at the fingertips of rights holders, against those who violate professional obligations and deontological principles. Thus, mistakes committed during the exercise of the profession attract the civil assassination of the culprit. The need to engage medical and medical staff in general is warranted by guaranteeing the right to health. Certainly, the civil liability of medical staff does not remove criminal responsibility, and they can coexist.

As a form of civil tort liability, the responsibility of the medical staff to be drawn must meet the legal requirements in the matter, so there must be an illicit deed, an injury, a causal link and guilt.

Having the legal obligation to close malpractice insurance for professional civil liability for injuries caused by the medical act, malpractice insurance plays an important role in the work of the professionals, the lack of which can distort the activity of the professional who, for fear of being sued for the potential harm that would cause its patients, would be extremely reluctant to take any risk.

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