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CIVIL LIABILITY IN MEDICINE IN THE LEGAL SYSTEM OF THE REPUBLIC OF NORTH MACEDONIA

Abstract: *The Macedonian legal system does not contain special rules on the liability of medical institutions and medical staff for damage that is caused while providing health services. This implies that the general rules of civil liability, which can be found in the Macedonian Obligation Relations Act (ORA), apply to professional liability of physicians and medical institutions. The comparative law shows that the rules of contractual and non-contractual liability, fault and strict liability as well as vicarious liability can be applied in cases of medical liability. The aim of this paper is to present the existing rules on liability in the Macedonian legal system that may apply in cases of civil liability in medicine, as well as to present cases involving different kinds of liability and analyze the specific differences among them. A clear distinction among different types of liability is essential for deciding which liability rules apply in a particular case: the rules on contractual liability or non-contractual (tort) liability. The legal relationship between a patient and a physician is primarily a contractual relationship and, in these cases, a medical treatment contract is the legal ground of the patient's and the physicians' rights, duties and obligations. The application of the fault liability rules is predominant in comparative law but the mass usage of medical devises and the introduction of high technology into medicine in general have resulted in the tendency to increase the application of strict liability in practice. In this paper, the author addresses the following questions: which of these tendencies and cases are accepted in the Macedonian legal system, and under what conditions are they applied in the Macedonian legislation and in practice.*

Keywords*: civil liability in medicine, fault liability, strict liability, patient, physician, pecuniary damages, non-pecuniary damages.*

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1. Introduction

Generally speaking, compensation for medical injury can take place in three ways: through the social insurance system including funds, through private insurers' schemes, and through the liability system (Dute, 2004: 474). The civil liability for damage in medicine is a relatively new institute, specially having in mind that the number of damage claims against doctors and medical institutions in the comparative law has significantly increased in the second half of 20th century. Legal scholars point out a few reasons that may explain the tendency of increased number of medical malpractice cases. The first reason is depersonalization of the doctor-patient relationship and its transformation in a pure business relation, as a result of the increased number of medical facilities and providers of health services (Klarić, 2003: 376). Other reasons that are postulated in legal theory are the excessive expectations of the patients as a result of the progress in both medicine and technology, the increased number of medical malpractice cases as a result of diagnostic error, inadequate or negligent treatment, and the existence of liability insurance for the doctor and the health institution (Klarić, 2003: 377).

2. Legal sources of civil liability in medicine

The legal provisions on health care and provision of healthcare services are contained in medical law. In legal literature, there are two definitions of the term *medical law*. In a narrow sense, medical law includes the legal provisions that regulate the relationships arising from performing medical activities. In a broad sense, medical law also includes the provisions regulating trade and prescription of medicines, provisions on professional liability insurance, and provisions on medicines and health supplies (Klarić, 2003: 378).

According to the narrow definition, the legal sources of medical law are diverse legal provisions that fall into different branches of law. In general, most of these provisions regulate the provision of health services. We may first refer to the Constitution of the Republic of North Macedonia because it contains a few provisions that can be classified as part of Macedonian medical law. Article 39 of the Constitution provides as follows: "*Every citizen is guaranteed the right to health care. Citizens have the right and duty to protect and promote their own health and the health of others*."[1]

1 Article 39, Constitution of the Republic of N. Macedonia, available at https://www.sobranie.mk/the-constitution-of-the-republic-of-macedonia-ns_article-constitution-of-the-republic-of-north-macedonia.nspx(accessed 17.08.2019)

Most of the provisions on health care and services are contained in the Health Protection Act (HPA).[2] Article 152 of this Act provides that the employees in the healthcare sector have ethical, professional and civil (material) liability, and that the health care institution is obliged to insure its employees against liability for damage that may be caused in the course of providing healthcare services. Article 152-a HPA states: "Healthcare workers and co-workers[3] shall be obliged, in the course of their operation, taking actions, and conduct, to apply and observe the principles and rules of conduct and operation determined by the Minister of Health by means of a protocol, pursuant to Article 27 paragraph (5) of this Law, for the purpose of ensuring application and observance of the principles of legality, professional integrity, efficiency, effectiveness and dedication in the performance of their official duties." The Act further specifies that a healthcare worker/co-worker "shall be obliged to perform the works and duties conscientiously, professionally, efficiently, duly and timely in accordance with the Constitution, law and ratified international agreements", that he/she is obliged "to do his/her work impartially, not to be guided by his/her personal financial interests, not to abuse the authorizations and the status of a healthcare worker, that is, a healthcare co-worker, and to protect the personal reputation and the reputation of the institution where he/she is employed", and that professional chambers (the Doctors' Chamber, the Dentists' Chamber and the Pharmaceutical Chamber) "shall adopt a Code of Professional Ethical Duties and Rights" (Article 166 HPA).

According to Article 180 of the Health Protection Act, the healthcare worker and co-worker shall be personally liable for the performance of job-related duties and activities. Along with personal liability, this law also introduces disciplinary liability of healthcare workers and co-workers (Articles 181-193 HPA) and the civil (material) liability (Article 194 HPA). Within the scope of disciplinary liability, Article 186 (7) HPA provides a type of disciplinary offence designated as "causing

2 Health Protection Act, "*Official Gazette of the Republic of Macedonia*" nos. 43/2012, 145/2012, 87/2013, 164/2013, 39/2014, 43/2014, 132/2014, 188/2014, 10/2015, 61/2015, 154/2015, 192/2015, 17/2016, 37/2016 and 20/2019 and "*Official Gazette of the Republic of North Macedonia*" no. 101/2019.

3 These terms are defined in the Health Protection Act: "Healthcare worker" is a person who provides health services in the delivery of a particular healthcare activity and is entered in the register of healthcare workers (doctor of medicine, doctor of dental medicine and pharmacist who holds a university degree or who have completed academic integrated studies with 300, that is, 360 ECTS in the field of medicine, dental medicine and pharmacy, healthcare workers with a two-year postsecondary school or higher vocational education or with 180 ECTS in the field of medicine, dental medicine and pharmacy) and healthcare workers who hold a high school degree' (Article 15, point 7 HPA); "Healthcare co-worker" is a person who holds a university degree and independently carries out particular activities within the healthcare activity in cooperation with the healthcare workers." (Article 15, point 8 HPA).

greater material damage", but the provision does not specify who the injured person is: the institution or a third person who is subject to medical services.

Article 194 HPA prescribes that a healthcare worker/co-worker "shall be liable for the damage he/she has caused at work or in relation with the work in the healthcare institution, intentionally or due to excessive negligence." On the other hand, "if a healthcare worker/co-worker suffers damage at work or in relation with work, the healthcare institution shall be obliged to compensate the damage in accordance with the law" (Article 199 HPA). These provisions refer to the mutual relationship between the healthcare worker/co-worker and the healthcare institution.

The Act on Protection of Patients' Rights,[4] adopted in 2008, is considered to be a milestone in the field of human rights related to patient care; it provides an excellent basis for the promotion of patients' rights (Apostolska & Tozija, 2010: 19). Although it outlines the patients' and providers' rights and obligations, as well as the mechanisms for protection of these rights, there is lack of provisions regarding liability for damage caused by the health institution while providing health services.

However, given the fact that the activity of healthcare personnel is considered to be a professional activity, the standard of care in case of providing professional activity is regulated in the Obligation Relations Act (ORA)[5]: "*When performing an obligation relating to their professional activity, a party of the obligations shall be bound to act with increased standard of care, according to the professional rules and customs (standard of care of a good expert*" (Article 11 (2) ORA). In order to define the obligations of professionals, the Act uses the standard of care of a good expert. Professionals have a duty to exercise the level of care that a reasonably prudent person in their line of work would exercise. Naturally, the specifics of care depend upon the practice area. Any act or omission by a physician during the treatment of a patient that deviates from accepted norms of practice in the medical community and causes an injury is considered to be medical malpractice and ground of fault liability. A plaintiff must show that the physician deviated from the level of care of a reasonably prudent person in the same position. The standard of care in our law is set on objective bases, which means that the conduct of the professional is compared to the abstract reasonably prudent person

4 Закон за заштита на правата на пациентите, (Act on Protection of Patients' Rights) *Сл. весник на Р Македонија* бр.82/2008, 12/2009, 53/2011, 150/2015; available at. http://zdravstvo.gov.mk/zakon-za-zashtita-na-prava-na-pacienti/(accessed 10.04.2019).

5 Закон за облигационите односи (Obligation Relations Act), *Сл. весник на Р Македонија* бр. 18 од 5.03.2001 г.

in the same position. It is not compared to the personal characteristics of the professional.

The liability for damage caused during the performance of healthcare activity is also regulated by by-laws. For example, in this paper, we refer to the "Rulebook on immunoprophylaxis and chemoprophylaxis of persons subject to these measures, the manner of instituting these procedures, and keeping records and documentation"[6], which the author came across in the analyzed case law.[7]

Ethical rules and medical profession rules are a significant segment of medical law. Although these rules rank lower than legal provisions in the hierarchy of legal norms, in some legal systems they are placed in the rank of legal rules. This is achieved by envisaging legal provisions which regulate that the inobservance of these rules will be subject to criminal and civil sanctions (Klarić, 2003: 379).

In the Macedonian legal system, there are general and specific principles that are the base for doctors' ethics. They are envisaged in the Macedonian Codex of Medical Deontology.[8] Regarding the relationship between the physician and the patient, the emphasis is on the duty of the physician to perform his professional duty conscientiously, precisely and responsibly, regardless of age, sex, religion, nationality, race, political affiliation, sexual orientation, disability and socio-economic status, and his personal attitude towards the sick and his family. The physician should consistently keep up with the achievements of medical science and the principles of professional conduct, and freely choose the method of treatment. When deciding on the treatment, one is obliged to rely on knowledge and conscience, and to be independent of various influences or inappropriate desires of patients, relatives and others (Article 19 of the Medical Deontology Codex).

3. Prerequisites of liability in the health care sector

As previously mentioned, apart from the liability mechanisms for compensation of damage, there are two models for compensation of damage: the social insurance system and the private insurers system. In these two models for compensation of damage, the central issue is whether the insurance conditions

6 Правилник за имунопрофилакса, хемиопрофилакса, лицата кои подлежат на овие мерки, начинот на изведување и водење на евиденција и документација, *Службен весник на Република Македонија* br 65/2010, available at http://zdravstvo.gov.mk/wp-content/uploads/2012/12/imunizacija-pravilnik.pdf (accessed 10.04.2019).

7 This Rulebook was used as as legal source in Decision of the Basic Court in Shtip P4-46/16 from 16.11.2018.

8 Кодекс на медицинска деонтологија (Codex of Medical Deontology), Лекарска комора на Македонија, adopted on 5 June 1992, Available at http://www.lkm.org.mk/mk/zapis.asp?id=278, (accessed 08.04.2019).

have been met; how the injury was caused is of little or no relevance. On the other hand, the situation is completely different when it comes to the liability model for compensation of damage in the healthcare system because this model entails that damage/injury can only be compensated if a person or institution can be shown to be liable; in general, it must be demonstrated that an error has been made and that the patient's injury was caused by that error (Dute, 2004: 480). In the text that follows, the mentioned prerequisites of liability will be elaborated, starting from defining the subjects in the liability model as a *conditio sine qua non* for every case of liability.

3.1. Subjects

According the Macedonian legal system, the healthcare activity is an activity of public interest "which ensures health protection and which covers measures, activities and procedures that, in accordance with the evidence-based medicine and with the use of health technology, are applied for maintenance and promotion of health, for prevention, early detection and eradication of diseases, injuries and other work and environment related health disorders, for timely and efficient treatment, as well as for health care and rehabilitation". Healthcare services are provided at primary, secondary and tertiary level of health protection, primarily provided by healthcare workers but particular activities may also be performed by healthcare co-workers who meet the requirements under the law (Article 12 HPA). The network of healthcare institutions provided and organized by the Republic of N. Macedonia comprises public and private healthcare institutions that perform the activity on the basis of a license (Article 28 (1) HPA).

The providers of healthcare services (licence holders) are the legal entities that may appear as a party (the tortfeasor) in lawsuits involving liability of healthcare institutions. Liability issues may arise out of a number of different relations, involving a doctor and a patient, a doctor and a hospital, or a hospital and a manufacturer or seller of medical products (Wendehorst, 2004: 261).

Liability in the healthcare sector may be contractual and tortuous liability, and it is very difficult to draw a strict borderline between the two. There are opinions in legal theory that these two categories "should not be seen in stark contrast to each other but as two opposite ends of liability based on fault which are connected by a chain of intermediate stages" (Koch & Koziol, 2004: 89) If we analyze the cases of liability through the prism of contract liability, the healthcare institution is one of the contract parties and it is liable under the contract liability rules. In cases of tortuous liability, the legal tortfeasor is also the healthcare institution. The Macedonian tort law contains liability provision that is in fact a general provision governing "the third party liability of

the employer for damage caused by the employee during work or related to work, except in cases when the employer will prove that the employee acted according to the profession rules and practices (rules on vicarious liability)" (Article 157 (1) ORA). The vicarious liability does not require fault on the part of the liable party, who instead has to account for the misbehavior of another. We consider these provisions on vicarious liability to be applicable in the cases of liability in the healthcare sector, where the healthcare institution appears as an employer and the healthcare worker/coworker appears as an employee. In addition, there is a provision in Macedonian tort law that provides a legal opportunity for parallel liability of both the employer (healthcare institution) and the employee (healthcare worker/coworker) in cases where the damage was caused intentionally (Article 157 (2) ORA). The court practice in these cases shows that the plaintiffs often claim damages from the healthcare institution because the compensation is more likely to be awarded when the case involves an institution (rather than an individual). On the other hand, in cases where the employer has compensated the damage caused by the employee with intention or gross negligence, the employer is entitled to seek redress from the employee[9] with a limitation period of six months, starting from the day the compensation was paid (Article 157 (4) and (5) ORA).

In healthcare liability cases, the plaintiff is the patient himself. But, in case of the patient's death or severe disability, the plaintiff may also be a family member (the patient's spouse, children and parents). According to the Macedonian tort law, certain family members are entitled to a fair monetary compensation, which is determined by the competent court. The cycle of these family members is determined by the law; it primarily includes the patient's spouse, children and parents but, in specific circumstances, it may also include the patient's brothers and sisters, grandparents and grandchildren, as well as the patient's extramarital partner, but only provided that there was a permanent life-long community between these persons and the deceased/ injured person (Article 190 ORA).

3.2. Wrongful act

There is large number of activities that can result in causing damage to another person while providing healthcare services. These activities are regulated by the healthcare protection regulations, and the legal theory provides systematization on this matter (Klarić, 2003: 397).

The term healthcare malpractice was introduced in legal theory very early. It is known in the Roman law, where it had broader meaning and it incorporated inexperience, negligence and not providing help. The term *medical malpractice*

9 Similar regulation is part of the Croatian tort law. (See: Klarić, 2003:397).

was first introduced in the modern legal literature in the mid-20th century but, in this period, the term was not defined by legal theory and it was not part of the legislation. Rudolf Virchow was the first among scientists to try to define what medical malpractice is, pointing out that malpractice should be considered to be a failure to comply with accepted standards of medical practice due to lack of required duty of care (Knežić & Dabić, 2009: 162). Nowadays, there is no doubt that the legal nature of the term *medical error* is not primarily legal but, within the civil liability of a physician, it acquires a nature of civil delict (tort); thus, in conjunction with damage and fault (or irrespective of whether it exists), it results in liability for medical malpractice.

4. The legal nature of the relationship between the healthcare provider and the patient

The primary question to be answer regarding the legal nature of this relationship is if this relationship is of private or public nature. The prevailing standpoint in legal theory in developed countries is that the relationship between the doctor and the patient has the nature of private relationship or, to be more exact, it is civil law relationship (Knežić & Dabić, 2009: 48; Klarić, 2003: 383). Exception is encountered in the French law and in some of the Swiss canons, where the relationship between the health service user and public hospitals is considered to be a public-law relationship of an administrative-law nature. In these systems, the doctor is considered to be a public servant and, in cases involving damage compensation, there is administrative court jurisdiction (Klarić, 2003: 383).

The next question is whether it is a contractual or non-contractual relationship. The prevailing opinion in the legal doctrine is that in most cases this relationship is based on contract, but there are cases involving non-contractual relationship (e.g. emergency). There are some theories that *negotiorum gestio* (as a type of obligation) arises in these cases (Klarić, 2003: 384).

Another question concerns the legal nature of this contract as there are different classifications in legal theory. In the French law, this contract is known as a contract *sui generis*. In German, Austrian and Greece law, it is known as a service contract. In Swiss law, it is known as a contract of mandate (Radišić, 1992).

There is no doubt that it is an unnamed contract and it is not regulated with specific provisions within the legal systems. In Serbian legal literature, it is designated as a patient treatment contract, although it is also mentioned that treatment in a narrow sense is only one of many medical services and that the term does not include examination, diagnosis, cosmetic surgery, sterilization, termination of pregnancy, and others (Klarić, 2003: 384).

In German legal literature, it is designated as a contract of medical treatment. Only in the Dutch legal theory and Dutch Civil code this contract is found as a named contract – contract of medical treatment, and it is regulated with special provisions.[10]

The relationship between the patient and physician in the Turkish law is considered to be based on contract, classified as a contract of mandate that can be concluded as an oral or as a written contract between the patient and the physician (Özsunay, 2007: 355). The Turkish court practice also considers this contract to be a contract of mandate.[11] If the doctor made a medical intervention on a particular person in the absence of such a contract, then his actions would be considered as unlawful, harmful actions as one of the conditions for the occurrence of non-contractual liability (Unver, 2016: 61).

We can conclude that different legal systems and doctrines have different views on the legal nature of the contract. On the other hand, we can agree that the determination of the legal nature of an agreement can also be seen as a question that depends on the specifics of the case. In practice, this implies the following interpretation: in the contracts for providing specific health services, the content of the undertaken obligations has to be taken into account, especially the type and purpose of the health services. At the end, this means that different contracts for providing healthcare services could have different legal nature. Some of these contracts have been established in theory and in practice as special types of contracts (for example, the contract for making a dental prosthesis, performing a cosmetic surgery, laboratory examination, etc.). All of these contracts are in fact considered to be contracts for specific work because in all these cases the physicians are obliged to achieve a certain result (Klarić, 2003: 385).

The essential part of the content of every contract for healthcare services is the obligation laid down by the law that the medical intervention should be carried out according to the rules of the medical profession and the moral and ethical principles of the medical profession. A contract for medical treatment obligates the doctor to exercise reasonable and comprehensive professional care and skill, which is determined on the basis of objective standards of expert behavior. Medical practitioners are required to come up to the standard of a prudent and experienced specialist in their respective area of expertise, which is determined according to the state of science at the time the injurious behavior occurred (Koch & Koziol, 2004: 97). Every activity of the physician that is contrary to these

10 Article 446-468 of the Dutch Civil Code, Book 7 (special contracts).

11 Turkish Court of Cassation, Decision from 6 July 1964, E 964/37, K 40 according to Özsunay, E. (2007). Medical Liability and Liability of Health Institutions in Turkish Law, *European Journal of Health Law* 14, pp. 355.

rules and principles constitutes a breach of contract and a civil wrong (delict) at the same time. On the other hand, this creates legal bases for applying the rules of both contractual and tortuous liability (Radišić, 1992: 103).

Regarding the application of the liability rules to a certain case, the choice is made by the plaintiff himself. The plaintiff will determine which rules the claim for compensation will be based on. The legal doctrine points to the advantages of basing these requirements on the rules of tortuous liability: longer periods of limitation, greater scope, the compensation for non-pecuniary damage through tortuous liability rules in legal systems where non-pecuniary damage is not provided in the case of contractual liability, and other advantages (Klarić, 2003: 390).

Most scholars consider the tortuous liability the most adequate type of liability in cases of liability in the medical sector, but the question to be addressed is whether fault liability or strict liability is a more appropriate base for the liability in the health sector.

In theory, the liability of the physician is always based on the fault of the doctor, and fault liability rules apply in every case, regardless of whether it is contractual or tortuous liability (Radišić, 2007: 90). In the early case-law of the Yugoslav courts, there were court decisions in which medical activity was treated as a dangerous activity and the rules of strict liability were applied to cases of physicians' liability. This practice was interrupted by decisions of the Federal Court of Yugoslavia and the supreme courts of the republics and provinces (Radišić, 2007: 90). One of those decisions was made by the Supreme Court of Serbia, which states: "*A medical institution that performs medical interventions can only be held laible for the consequences of interventions that result from the unprofessional and careless or improper treatment performed by its employees, i.e. for consequences that may be attributed to the fault of doctors and other medical personnel for acts which were not in accordance with the rules of medical science.*"[12]

In Croatian court practice, a decision by the Constitutional Court of the Republic of Croatia states: *"The hospital is liable for medical malpractice based on the principle of presumed fault, which means that the hospital must prove that the employee acted in accordance with the rules of the medical profession and that the damage did not occur because of the negligence of the physician performing the operation ...*

12 Decision of the Supreme Court in Serbia, Rev.2066/80, of 14.01.1981, *Pravni život*, br. 11/1981, str.120-121, cited according to Radišić, J. (2007). Odgovornost zbog štete izazvane lekarskom greškom u lečenju i u obaveštavanju pacijenta. Beograd: Nomos Izdavačko preduzeće DOO, стр. 91.

The first-instance court incorrectly states that the liability of the medical institution for a medical malpractice is decided on the basis of the principle of proven fault. "[13]

In Macedonian law, the general provision regarding the standard of due care that the healthcare employee is obligated to provide to the patients is contained in the Obligations Act. As already mentioned, the patient-physician relationship is considered to be a professional relationship and the physician is obligated to act as a "good expert" in the field. The term good expert is a legal standard or a medical "standard of care", and it entails the degree of care and skill of the average health care provider who practices in the provider's specialty, considering the medical knowledge that is available in the field. The standard of care is typically based on the hypothetical practices of a reasonably competent health care professional in the same or similar community. This shows that the abstract concept of standard of care is accepted in the Macedonian law as well as in Macedonian legal theory, i.e."...*the abstract rule that specifies what properties a person should have is more acceptable than considering what properties he personally possesses*"(Галев & Анастасовска, 2009: 679).

On the other hand, regarding the burden of proof for the physicians' fault, the plaintiff has the burden of proof in cases he claims that the defendant (the physician) caused the damage with fault or gross negligence. In cases of ordinary negligence, the burden of proof rests with the defendant who has to show that the standard of care was met at that moment.[14]

Although it is common ground in jurisprudence and legal theory that indemnity liability in health care should be adjudicated on the principle of fault, there are also views that it is wrong to consider liability within health care activity solely through the application of fault liability rules, thus ruling out the possibility of applying the rules of strict liability (Crnić, 2009: 84).

We consider that our law provides a legal possibility to apply both grounds of liability. According to Macedonian law, strict liability is not regulated by the principle of numerous clauses but as liability arising from a dangerous object, or from carrying out a dangerous activity. One of the characteristics of this type of liability is the assumption of causality; namely, the damage arising from an object, movable or immovable, whose position, use, feature or its very existence present an increased risk of harm to the environment (dangerous object), or an activity that can be considered to present an increased risk of harm to the environment (hazardous activity), is assumed to originate from that object

13 Decision of the Constitutional Court of Croatia U-III -3002/2005 of 21.11.2007, cited according to Crnić I. (2009). Odgovornost liječnika za štetu. Zagreb: Organizator стр. 84.

14 Article 145 (2and 3) of the Obligations Act.

or activity, unless it is proved that the cause of the damage lies in the plaintiff himself, in a third person, or that it occurred due to force majeure.

The theoretical standpoints in Macedonia appear to be in line with the established case-law. Namely, in the jurisprudence of Macedonian courts, we find that: "*When it is established that the cause of bodily harm to a juvenile plaintiff is the compulsory vaccine that the victim received at the health center, and the control is carried out by the Ministry of Health, solidarity liability for non-pecuniary damage incurred under the principle of strict liability exists in the person who applied the vaccine and in the person who controls the process.*"[15] On the other hand, we have come across a new court decision on a similar case of vaccine-induced damage. In this case[16], the judge found that the Ministry of Health "... *as a body that provides centralized supply of all vaccines in accordance with the mandatory and continuous immunization calendar and as a body that oversees the procurement and supply of vaccine health facilities and control over the legality and expertise of the work of the health organizations as well as the vaccination process itself, had not strict liability in the case*." This way the courts created a differing case law practice regarding joint and strict liability in cases of mandatory vaccination.

Based on the liability provisions provided in the Obligation Relations Act (ORA), the person liable for damage arising from dangerous object is the owner of the object, and the person liable for damage arising from dangerous activity is the operator (holder) of dangerous activity (Article 160 ORA). The rule on joint liability in the scope of the strict liability is contained in Article 163 (4) of the ORA, which states:"*If third person partially contributed to the arise of the damage, that person is liable to the plaintiff along with the owner of the dangerous object, and he has the obligation to compensate the damage in proportionate amount with his fault*."[17] Within strict liability, there are three bases of exoneration (Article 163 ORA):

1. Force majeure
2. Exclusive fault of the claimant
3. Partial exoneration of strict liability in cases of partial contribution of the claimant to the occurrence of damage.

15 Decision of the Court of Appeal in Stip, GZ. n. 358/2011 from 12.05.2011 and the Supreme Court of R.M. Rev. no. 879/201 of 3.05.2013 cited according to Bulletin No. 8 of Court of Appeal in Stip, June 2014.

16 Decision of the Basic Court in Stip, P4-46/2016 of 16.11.2018

17 The general rule on joint liability is contained in Article 195 of the Obligation Relations Act (ORA).

Legal literature emphasizes that there are medical, surgical or gynecological procedures that may cause harm to the health service user during regular medical procedures only because of their medical nature and procedures that may endanger one's life or health (Crnić, 2009: 93).

In the comparative case law we find what activity may be designated as a dangerous activity: *"An activity is considered to be increased danger only if by its regular course, by its very technical nature, or the manner in which it can be performed, it is endangering human health or property, so the endangering itself requires increased standard of care from the person performing the activity."*[18] In addition to such views, legal literature includes the decision of the Constitutional Court of the Republic of Croatia, which states that strict liability is generally provided for all damage stemming from objects and activities with an increased risk to the environment and that in each particular case it is for the court to assess whether the object or activity associated with the damage was actually a dangerous object or a dangerous activity.[19]

5. Concluding remarks

Today, there are three established models for compensation of damage in the field of medicine: compensation through the social insurance system, compensation through private insurers' system, and compensation through the civil liability system. This article focused on the liability model for compensation under Macedonian law. This model comprises provisions on liability that are found in *lex specialis* referring to health law in our legal system. The analysis of the Health Protection Act has shown that there is lack of regulation regarding the civil liability of the healthcare institution and/or the healthcare workers/co-workers for the damage caused to third persons that use these health services.

The analysis of the Act on Protection of Patients' Rights showed that although it outlines the patients' and providers' rights and obligations, as well as the mechanisms for protection of these rights, there is also a lack of provisions regarding liability for damage caused by the health institution while providing health services.

In terms of theory and court practice, the provisions contained in the Obligations Act (as general tort law provisions) appear to be sufficient and they have been successfully used to regulate cases of medical malpractice. Although fault

18 Vs, Rev-298/88, of 13.10.1988. PSP-43/76, cited according to Crnić I. (2009). Odgovornost liječnika za štetu, Zagreb: Organizator, стр. 94.

19 Decision of the Conitutional Court of Croatia U-III-1062/2005 од 15.11.2007, cited according to Crnić I. (2009). Odgovornost liječnika za štetu. Zagreb: Organizator, стр. 94.

laibility is primarily used as the legal ground for establishing liability in such cases, the analyses have shown that strict liability can also be the legal ground for determing the compensation for injuries or harm that occured in the course of providing health care services.

We strongly believe that the established system for regulating medical malpractice will serve as an appropriate incentive to health care providers. In this way, liability rules serve their primary preventive function. But, we also recognize the reasons in favor of using strict liability rules, which are advocated by the legal doctrine and some judges in our legal system. These reasons are often motivated by the wish to provide full compensation for victims, especially in cases where the nature of the provided medical treatment or other kind of activity is dangerous and entails inherent risks.

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ГРАЂАНСКА ОДГОВОРНОСТ У МЕДИЦИНИ У ПРАВНОМ СИСТЕМУ РЕПУБЛИКЕ МАКЕДОНИЈЕ

Резиме

Упоредно право указује да се правила о уговорној и вануговорној (одштетној) одговорности, одговорности за лекарску гршку и објективној одговорности, као и одговорности за радње других, могу применити у случајевима одговорности здравствених установа и медицинског особља. Циљ овог рада је да представи постојеће законске одредбе о одговорности у македонском правном систему које се могу применити у случајевима грађанске одговорности у области медицине, да анализира случајеве који укључују различите врсте одговорности и прикаже разлике међу њима. Утврђивање специфичних разлика између различитих врста одговорности неопходно је у процесу одлучивања о томе која правила важе у конкретном случају: правила о уговорној или вануговорној одговорности. Правни однос између пацијента и лекара је првенствено уговорни однос. У овим случајевима, уговор о лечењу је основ права, дужности и обавеза како пацијента тако и лекара. У упоредном праву преовладава примена правила о одговорности за лекарску грешку. Међутим, масовна употреба медицинских уређаја и увођење високе технологије у медицину довели су до повећане примене објективне одговорности у пракси. У овом раду, аутор настоји да одговори на следећа питања: које од ових тенденција су прихваћене у македонском правном систему, и под којим условима су примењене у законодавству и пракси?

Македонски правни систем не садржи посебна правила о одговорности здравствених установа и медицинског особља за штету насталу приликом

пружања здравствених услуга. Македонско медицинско право је ограничено у погледу броја и обима одредаба о професионалној одговорности лекара и здравствених установа и накнади штете настале услед повреде ових права. У овим случајевима се примењују општа правила одштетног права, садржана у македонском Закону о облигационим односима (ЗОО). Доминантна основа одговорности у овим случајевима је одговорност на основу кривице, која почива на лекарској грешци, као посебном предуслову одговорности. Међутим, према македонској судској пракси, одредбе о објективној одговорности или одговорности без обзира на постојање или непостојање лекарске грешке, такође су признате као основ за одговорност.

***Кључне речи*:** *грађанска одговорност у медицини, грешка, објективна одговорност, лекар, пацијент, материјална штета, нематеријална штета.*