UDK 34(058)

ISSN 0350-8501

УНИВЕРЗИТЕТ У НИШУ
ПРАВНИ ФАКУЛТЕТ

ЗБОРНИК РАДОВА ПРАВНОГ ФАКУЛТЕТА У НИШУ

БРОЈ 85 | ГОДИНА LVIII | 2019

COLLECTION OF PAPERS FACULTY OF LAW, NIŠ

Nº 85 | YEAR LVIII | 2019

НИШ, 2019.

ЗБОРНИК РАДОВА ПРАВНОГ ФАКУЛТЕТА У НИШУ

Ниш, 2019.

Издавач
Правни факултет у Нишу

За издавача
Проф. др Горан Обрадовић, декан

Главни и одговорни уредник
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редовни професор Правног факултета Универзитета у Нишу

Штампа: Графика Галеб Ниш

Тираж: 120

Зборник радова Правног факултета у Нишу
под називом Collection of Papers, Faculty of Law, Nis је у пуном тексту доступан у HeinOnline бази података, EBSCO бази Legal Source, као и у бази Central and Eastern European Online Library – CEEOL.

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COLLECTION OF PAPERS, FACULTY OF LAW, NIS
NIŠ, 2019

Publisher:
Faculty of Law, University of Niš

For the Publisher:
Prof. dr Goran Obradović, Dean

Editor-in-Chief:
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Website: http://www.prafak.ni.ac.rs

http://www.ebscohost.com/public/legal-source
http://home.heinonline.org/titles/Law-Journal-Library/Collection-of-Papers-Faculty-ofLaw-Nis/?letter=C
Central and Eastern European Online Library – CEEOL

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II РАДОВИ СТУДЕНАТА ДОКТОРСКИХ СТУДИЈА / *PHD STUDENTS' PAPERS*

Уводна реч

Поштовани читаоци,

У фокусу броја 85/2019 Зборника радова Правног факултета у Нишу налазе се два научна рада из области медицинског права у којима су анализирани принципи у поступку трансплатације људских органа, као и цивилна одговорност у области македонског медицинског права. Такође, у броју који се налази пред вама налази се део научних радова који су настали као резултат учешћа на Међународној научној конференцији „Право и мултидисциплинарност" одржаној 12-13. априла 2019. године на Правном факултету у Нишу који су прошли рецензентски поступак. Сви радови прошли су процес двоструке анонимне рецензије.

У Нишу, фебруар, 2020.

Главни и одговорни уредник

Проф. др Ирена Пејић

Editor's Introductory Note

Dear Readers,

In this issue of the journal Collection of Papers of the Law Faculty, University of Niš (85/2019), the rubric In Focus comprises two scientific articles on Medical Law issues: the principles of human organ transplantation procedure, and civil liability of medical professionals under the Macedonian medial law. The other scientific papers published in this issue have been the result of participation in the International Scientific Conference "Law and Multidisciplinarity", which was held at the Faculty of Law, University of Niš, on 12-13 April 2019. Each article has been assessed on its own merits through the anonymous peer review process.

Niš, February 2020.

Prof. Irena Pejić, LL.D.

Editor-in-Chief

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ПРЕГЛЕДНИ НАУЧНИ РАД
10.5937/zrpfn0-23577

UDK: 347.51:614.2(497.7)
614.2
Рад примљен: 14.10.2019.
Рад прихваћен: 27.11.2019.

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).