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LEGAL CONTROL OF MEDICAL SECTOR IN SERBIA
30 YEARS AFTER FALL OF BERLIN WALL

Abstract

The fall of the Berlin Wall is a historical event whose consequences could be felt throughout Europe at various levels. In 1989 the word "freedom" became a key term, and "return to Europe" an overall formla for understanding this historical event. What began as individuals' effort to achieve freedom from lies and repression toward freedom of speech and art, three decades ago unstoppably opened a window to new scientific disciplines, at the same time developing and reinforcing some old ones. The latter was the case of medical law which focused on the issues concerning the very essence of medical sector and the actions of medical professionals. Medical law has become a field of cooperation, but also a field of "cold war" between doctors and lawyers. It took quite a long time for doctors to get used to the fact that their humane vocation is not capable of justifying every professional error and negligent treatment of a patient; that their medical procedures are also subject to legal control and that medicine must not do everything it is capable of doing. In the last decades of the 20th century, there were very few litigations against doctors and medical institutions in former Socialist Federal Republic of Yugoslavia, whose integral part was the Republic of Serbia. Legal options and criminal and civil liabilities of medical professionals existed, but were rarely used. Today, thirty years later, the situation in the Republic of Serbia is somewhat different. There is a variety of legal safeguards of patient rights, but they mostly remain unused. This paper shall analyze how the legal control of the medical sector in the Republic of Serbia has transformed 30 years after the fall of the Berlin Wall, which types of the legal control of the medical sector exist today, and whether the existing safeguards represent the necessary measure of protection of patients' fundamental rights.

Keywords: medical sector, Republic of Serbia, the liability of doctors, patient rights, the Berlin Wall

I. INTRODUCTION

After the fall of the Berlin Wall, political leaders were tasked with prompt shaping of novelties in politics, business and the society in socialist countries. As Roick opines, this meant that countries had to cope with at least two, if not three transformation processes at the same time:[1]

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political transformation (transfer from communism into democracy); economic transformation (transfer from planned to market economy), and in certain cases, state transformation (founding new national states in cases of disintegration, separation or disappearance of a state, as was the case with the Soviet Union, Czechoslovakia in 1993, Yugoslavia after 1991, etc.).[2] Serbia, which was one of the six republic of the Socialist Federal Republic of Yugoslavia (SFRY) at the time of the fall of the Berlin Wall, and now stands as an independent country, unfortunately had to undergo all three transformation processes simultaneously. The state transformation process began with the disintegration of Yugoslavia in the period from 1991 to 2003, and it was embodied in an array of conflicts between the nations that lived in it. The republics separated one by one, hostility between the nations increased and after several years of civil war, what emerged were independent countries and several nations between which there has always been a degree of mutual tensions. Serbia, which was in a way Yugoslavia's successor, in 2006 suffered the secession of Montenegro and its departure from the then State Union of Serbia and Montenegro[3], and for the past decade it has been fighting against the unilaterally proclaimed independence of Kosova and Metohija, so it can be concluded that Serbia is still affected by the process of Yugoslavia's transformation, which was initiated after the fall of the Berlin Wall. How devastating that is, can be seen in the fact that even today, 30 years after the fall of the Berlin Wall, Serbia still suffers the consequences of unfinished transformation processes in all fields, only one of which is the healthcare system and medical sector organization. Medical sector is particularly important because of its field, which is care for people's life and health. However, the inefficiency and "bureaucratization" of the medical sector, which was typical for socialism almost as much as the "commercialization" of medical services which is typical of medical sector today, had an almost equal effect on the deterioration of patient's position and disrespect of their rights. It is often overlooked that medical protection of a person's life does not serve only to the personal interests of individuals, but also to public, social interest. A doctor into whose hands people put their life and health has to allow a strict evaluation of his/her actions. However, this control does not aim at limiting the freedom of medical professionals that serves patients' interests, but rather to force doctors to adhere to the current professional standard and the principles of medical ethics. In other words, doctors are expected to act knowledgeably, ethically and with due care. This paper shall attempt to provide an insight into the way the healthcare system in the Republic of Serbia was necessarily transformed after the fall of the Berlin Wall due to the multiple transformations of the state, with a particular accent on the organization of patient rights protection, and mporta the legal control mechanisms for the medical sector in the Republic of Serbia exist today and how efficient they are.

II. FIRST DECADE AFTER FALL OF BERLIN WALL

Even though 1989 and the fall of the Berlin Wall was indirectly significant for Yugoslavia and Serbia, this event failed to bring them democratization or liberalization. SFRY fell apart and Serbia continued as a member of a new, third Yugoslavia, the Federal Republic of Yugoslavia

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[1] Michael Roick, *Cena slobode - 30 godina od pada berlinskog zida,* a text authored by the Director of the Western Balkan Office of the Friedrich Neumann Foundation, available at: <https://talas.rs/2019/11/01/cena-slobode-30-godina-od-pada-berlinskog-zida/ >, accessed 03. 01. 2020.

[2] *Ibid.*

[3] The State Union of Serbia and Montenego was a state union composed of the republics of Serbia and Montenegro. It existed between Feb. 4, 2003 and May 21, 2006, when Montenegro voted for independence at a referendum.

(FRY) which emerged after the proclamation of the Constitution of the Federal Republic of Yugoslavia on April 27, 1992.[4] Before than, the Republic of Serbia in 1990 passed a Constitution[5] which practically sets the foundations of new healthcare and insurance systems in the Republic of Serbia, so the healthcare and health insurance regulations on the republic level were harmonized accordingly. In the midst of the disintegration of the SFRY, the Law on Healthcare[6] of January 1990 establishes the Healthcare and Health Insurance Fund which as a legal successor assumes the assets, rights and obligations of the Republic Self-Governing Interest Healthcare Community (SIC) in Belgrade.[7] Serbia no longer has healthcare SICs[8]; instead of them, it formed funds. There used to be 18 municipal healthcare and health insurance funds in Serbia (each covering multiple municipalities' territories), and one city healthcare and health insurance fund (for the territory of the city of Belgrade).[9] Then, the 1992 Law on Health Insurance[10] discontinued the Republic Healthcare and Health Insurance Fund, the Provincial Healthcare Funds in Novi Sad and Priština, and municipal healthcare and health insurance funds in the territory of the Republic of Serbia,[11] and in April 1992, the Republic Health Insurance Institute was formed, assuming the property of the city, provinces and the Republic of Serbia, transferred to it as the property of labour communities of healthcare SICs on the date the Law on Social Sectors came into effect.[12] Unlike complete decentralization that existed in the domain of healthcare and health insurance in the period of "free labour exchange" within SFRY, the period after 1992 is characterized by centralization. Therefore, for example, health insurance in the entire territory of the Republic, used to be handled by a single organization – the Republic Health Insurance Institute and its 30 branches (with offices).[13] Then, after the disintegration of the FRY and the formation of the state union of Serbia and Montenegro in 2003, the entire jurisdiction in the domain of healthcare and social insurance was transferred to the member states.

Therefore, all these changes on the state level that occurred after the fall of the Berlin Wall left consequences on the very organization of healthcare and health insurance as much as on the relationship between doctors and patients. Minimum investments into the healthcare system due to the general financial crisis in that period led to the deterioration of the quality of medical

[4] The Federal Republic of Yugoslavia (FRY) was created by the dissolution of the SFRY. It was formed on April 27, 1992, by the decision of the SFRY Assembly, as a joint state of the Republic of Serbia and the Republic of Montenegro, and it existed until February 2003, when the state union of Serbia and Montenegro was created. Within the FRY, Vojvodina and Kosovo and Metohija had the status of autonomous provinces within the Republic of Serbia, but with much less authority than at the time of SFRY. More in: Vojin Dimitrijevic (ed.), *Ljudska prava u Jugoslaviji 2001. Pravo, praksa i pravna svest u Saveznoj Republici Jugoslaviji i međunarodni standardi ljudskih prava*, (Beogradski centar za ljudska prava, Beograd, 2002), p.24. <http://bgcentar.org.rs/bgcentar/wp-content/uploads/2013/04/ljudska-prava-u-jugoslaviji-2001.pdf > , accessed 3.01. 2020.

[5] The Constitution of the Republic of Serbia, "Official Gazette of the Republic of Serbia", No. 1/1990.

[6] Law on Healthcare," Official Gazette of the Republic of Serbia", No. 4/1990.

[7] Rajko Kosanović, Hristo Anđelski, (2015.), Basic Directions of Health Insurance Development in the Republic of Serbia (1922-2014). *Health Care, 44 (3),* p.62 onward.

[8] The 1971 Constitutional Amendments introduced self-governing interest communities (SICs) into the country's self-governing system. Constitutional amendment XXI provides the basic characteristics of SICs as places where "free labour exchange" takes place and where decisions are made on the basis of self-governing and social agreement. See: Rajko Kosanović, Hristo Anđelski, (2015.), p. 61.

[9] *Ibid.* p.64.

[10] Law on Health Insurance, "Official Gazette of the Republic of Serbia", No. 18/92.

[11] Rajko Kosanović, Hristo Anđelski, (2015.), p.62 onward.

[12] Law on Social Sectors, "Official Gazette of the Republic of Serbia", No.1/90.

[13] Rajko Kosanović, Hristo Anđelski, (2015.), p.65.

services, the absence of any transparency in the work of healthcare professionals, constant shortage of medications, the formation of unjustifiedly long waiting lists, spreading of corruption, and an additional sore spot was the fact that on an annual level, a great number of healthcare professionals left Serbia, which further restricted patients' access to healthcare.[14] When working, doctors complied only with the measures of their own profession, not taking into account a patient's personality or their psycho-social situation. Patients were completely subjected to their doctors' will, and there was no mentioning of the legal protection of the autonomy of patients' personality. Such paternalistic relationship between doctors and patients lingered until the end of the 20th century. Only a few laws in addition to the systemic laws – the Law on Healthcare and the Law on Health Insurance – regulated the entire field of healthcare in the Republic of Serbia.[15] Special legal norms on patient rights or protection did not exist, and even though legal options and criminal and civil liability of medical professionals existed, there are no specific data regarding the extent of their use, because neither courts nor other state bodies recorded such statistics, and court court bulletins and collections of court decisions available to the public did not include all verdicts, but only a few crucial ones.[16]

III. PERIOD AFTER 2000

When it comes to the respect of patient rights and the legal control of medical sector, the first serious steps in the Republic of Serbia were made in the first decade of the 21st century, when a new state regulation seemed to appear, slowly rising from the bog of authoritarian past. It could be said legislative changes in terms of the doctor-patient relationship in the Serbian healthcare began only in 2005, when the Serbian legislator felt the need for the first time to specifically and clearly label patient rights, to systematize and codify them. That is why amendments were introduced to the Law on Healthcare in 2005, concerning patient rights and duties, whereby patient rights were linked to human rights and placed in a separate section titled "Human Rights and Values in Healthcare and Patient Rights".[17] This way, instead of the previous paternalistic relationship, a partnership doctor-patient relationship was promoted, in which patients enjoy the position of a *subject*, not an object of medicine. The Law on Healthcare prescribes high moral, ethical and civil norms of conduct for both users and providers of healthcare services.[18] Also, this was the first law to regulate the institution of patient ombudmsan. Namely, the law

[14] In contrast, up to 1989, 8384 general and specialist healthcare institutions were opened, as well as 4425 dentist's offices. In addition, with the development of the road network, improved communications and a different social policy, healthcare has become available to a much larger number of people. More in: Latinka Perovic, et.al. (ed.), Jugoslavija u istorijskoj perspektivi, Helsinški odbor za lljudska prava u Srbiji, (2017), Beograd, p.352. <https://www.helsinki.org.rs/serbian/doc/jugoslavija%20u%20history%20perspektivi.pdf >, accessed January 3, 2020.

[15] Law on the Protection of the Population from Infectious Diseases, "Official Gazette of the FRS", No. 59/89 and "Official Gazette of the RS", No. 44/91, 53/93, 67/93 and 48/94, Law on the Protection of the Population from Infectious Diseases that Threaten the Entire Country, "Official Gazette of the FRY", No. 46/96, 12/98 and 37/02. as well as the Law on the Conditions for Taking and Transplanting Human Body Parts, "Official Gazette of the SFRY", No.63/1990.

[16] Statistics on the number of court proceedings for the period up to 1987 can be viewed with Jakov Radisic, in: *Profesionalna odgovornost medicinskih poslenika* (Institut društvenih nauka, Beograd, 1986.) p.90.

[17] Taken from: Jakov Radišić, *Medicinsko pravo* (Pravni fakultet Univerzitet u Beogradu i Službeni glasnik, Beograd, 2008) p.78.

[18] Law on Healthcare, "Official Gazette of the Republic of Serbia", No.107/05, 72/09 – state law, 88/10, 99/10, 57/11, 119/12, 45/13 – state law, 93/14, 96/15 and 106/15 basic text in effect and applied from Dec. 10, 2005.

prescribed patient rights, including the right to file a complaint. Concerning decision-making on patient complaints about provided healthcare services or failure to provide them, the law prescribed healthcare institutions' obligation to have a patient ombudsman.[19] Then, in 2006, the Serbian Medical Chamber was refounded, along with the chambers of other mportant professionals[20] and its status was defined by the Law on Chambers of Healthcare Professionals.[21] Since then, all medical doctors whose vocation is to work in the medical sector, defined by the Law on Healthcare, must be members of the Serbian Medical Chamber. The same year, the Chamber Statute defined courts of honour, thus legalizing the possibility to initiate an action for doctors' disciplinary liability before these courts, which will be discussed in more detail further on.[22] Intense legislative changes in the field of healthcare were continued in 2009, when several mportant laws in the field of new technologies in medicine were adopted: the Law on Infertility Treatment by Biomedically Assisted Fertilization Procedures[23], the Law on Organ Transplant[24], the Law on Cell and Tissue Transplant[25], as well as the Law on Transfusiology Activity[26] and the Law on Public Health.[27] This set of laws announced the long awaited changes in the field of health policy regarding respect for patient rights, which resulted in the adoption of the 2013 Law on Patient Rights[28], which regulated the rights of patients when using healthcare, the way of exercising and the protection of those rights, as well as other issues regarding the rights and duties of patients.[29] Two years later, the Law on Prevention and Diagnostics of Genetic Diseases, Genetically Conditioned Anomalies and Rare Diseases[30] was also adopted. For the first time, this law focuses on the legal significance of diagnosis, especially in rare diseases,

[19] Law on Healthcare (2005), Art. 39: "(1) A patient who has been denied the right to healthcare, that is, a patient who is not satisfied with the provided healthcare service, or the actions of a healthcare professional or other employee of a healthcare institution, may file a complaint to the healthcare provider who manages the work process or to a person employed in a healthcare institution performing patient rights protection activities (hereinafter: the patient ombudsman).

[20] In Serbia, the Medical Chamber was founded back in 1901, at a time when chambers were established in other European countries as professional associations, which could exercise self-regulation and control of their membership. However, in 1940, the further work of the LK was first frozen by the events of the war, and upon the end of the war came to an end. See more at: <http://www.lks.org.rs/content/cid106/istorija> accessed Dec. 12, 2019.

[21] Law on Chambers of Healthcare Professionals, "Official Gazette of the Republic of Serbia", No. 107/2005, 99/2010 and 70/2017 – Constitutional Court decision.

[22] See part 4.3. of this paper.

[23] Law on Infertility Treatment by Biomedically Assisted Fertilization Procedures, "Official Gazette of the Republic of Serbia", No.72/2009.

[24] Law on Organ Transplant, "Official Gazette of the Republic of Serbia", No.72/2009.

[25] Law on Cell and Tissue Transplant, "Official Gazette of the Republic of Serbia", No.72/2009.

[26] Law on Transfusiology Activity, "Official Gazette of the Republic of Serbia", No.72/2009.

[27] Law on Public Health, "Official Gazette of the Republic of Serbia", No.72/2009.

[28] Law on Patient Rights, "Official Gazette of the Republic of Serbia", No.45/13. During October and November 2012, one draft and one bill proposal on patients' rights and their protection were available to the professional public in Serbia. These were the Draft Law on Patient Rights Protection, drafted by the Ministry of Health and the Proposed Law on the Protection and Advancement of Patient Rights, proposed by MP Dušan Milisavljević, Chairman of the RS Committee on Health and Family. During November and December 2012, the Ministry of Health of the Republic of Serbia organized several public hearings on the Draft Law on Patient Rights Protection (in Kragujevac, Niš, Novi Sad and Belgrade). In Jelena Simić, Nevinost bez zaštite" ili jedno viđenje Zakona o pravima pacijenata, *Legal Records*, No.1 / 2013, p. 146.

[29] Article 1 of the Law on Patient Rights, "Official Gazette of the Republic of Serbia", no. 45/2013 and 25/2019 - state law.

[30] Law on Prevention and Diagnostics of Genetic Diseases, Genetically Conditioned Anomalies and Rare Diseases, "Official Gazette of the Republic of Serbia", No. 8/2015.

further legal consequences, time of actions and procedures, as well as the involvement of domestic and foreign laboratories. The most recent changes in the systemic laws in this domain – the Law on Healthcare and the Law on Health Insurance – were introduced in 2019, and the healthcare system has been centralized with jurisdictions within the Ministry of Health, the National Health Insurance Fund and the Institute of Public Health of Serbia "Milan Jovanović Batut".

IV. CURRENT LEGAL CONTROL MECHANISMS FOR MEDICAL SECTOR

Observed through the organization of healthcare system, medical sector today represents a very complex system which, among other types of control, is also subject to legal control. Such control is conducted primarily for the protection of patients and their rights as users of medical services within the healthcare system, so it can be observed from the aspect of patients' right to appropriate legal protection when exercising their healthcare rights. The laws regulating the field of healthcare envisage different safeguards of patient rights and control of healthcare institutions' work. Therefore, they can be court and out-of-court settlements, single-instance and multi-instance, individual and general legal protection.

As the highest legal act of the Republic of Serbia, the Constitution[31] guarantees everyone's right to equal protection of rights in a procedure established by law, which means equality of treatment and procedure provided for by law. This constitutional principle also applies to legal protection in the field of health[32], since it is always exercised before state authorities. The control of the provision of health services to patients and the operation of healthcare facilities is triggered, among other things, in one of the following ways:[33]

1. 1. by filing a complaint to a healthcare professional managing the work process or to the director of a health care institution, or to the founder of a private practice[34],
2. by filing a complaint to a counselor for the protection of patient rights,[35]
3. by contacting a local health council for advice when the patient is dissatisfied with the counselor's report,[36]
4. by demanding an internal and exteral quality assurance of professional work[37]
5. by filing a complaint about the work of healthcare professionals and healthcare institution to a healthcare inspection[38]

[31] Constitution of the Republic of Serbia, "Official Gazette of the Republic of Serbia", No. 98/2006.
[32] Article 36 of the Constitution (right to equal protection of rights and to legal remedy).
[33] By adopting a new Law on Health Insurance in April 2019 Law on Health Insurance, "Official Gazette of the Republic of Serbia", No. 29/2019. one of the safeguards in the domain of health insurance was abolished. Namely, until then, patients were able to address patient ombudmsna whose jurisdiction was regulated by the Law on Patient Rights. The offices of the ombudsman of insured persons were located in healthcare institutions where patients were able to obtain assistance very promptly (deleted Article 38, par. 2 and 3 of the Law on Patient Rights Protection). The cancellation of the ombudsman of insured persons is not a good move bearing in mind that the ombudsman was an officer of the National Fund of Health Insurance and that they had direct contact with patients.
[34] Article 30 of the Law on Patient Rights, "Official Gazette of the Republic of Serbia ", No. 45/2013 and 25/2019 – state law.
[35] *Ibid.*
[36] Article 42 of the Law on Patient Rights.
[37] Article 188 of the Law on Healthcare, "Official Gazette of the Republic of Serbia", No. 25/2019..
[38] Article 41, par 5 of the Law on Patient Rights and Article 18 of the Law on Inspection Control, "Official Gazette of the Republic of Serbia", no. 36/2015, 44/2018 – state law and 95/2018.

6. by filing a consensual or individual request to initiate a mediation procedure with a medical chamber,[39]
7. by initiating a court of honour proceeding before a regional medical chamber,[40]
8. when exhausting all the mechanisms of the general administrative procedure, patients may address the Ombudsman,[41]
9. by filing a lawsuit for damage compensation to a civil court,
10. by pressing criminal charges for the initiation of a criminal procedure against a doctor.

In the following part, we shall analyze only some of the given mechanisms of control of the provision of healthcare to patients and the work of healthcare institutions.

1. Counsellor for patient rights protection and health council

The 2013 Law on Patient Rights Protection ntroduced novelties into the name and organization of the institution of patient rights protection, according to which the protection is performed by a counsellor for patient rights protection and a local health council.[42] A counsellor for patient rights protection ensures patient rights protection by handling filed complaints and provides necessary information and advice regarding patient rights (Article 39, par. 2). A decision on the organization, financing and the conditions of patient counsellor's work is passed by a competent local self-government authority, in line with patients' needs and the capacities of a local healthcare service (Article 39, par. 4). The good side of this provision is that patient counsellor is not employed by or financially related to a healthcaare institution, which means they are independent in their work. In order to ensure patient counsellor's access to all healthcare institutions, the legislator envisages an official ID for patient counsellor, which they use as an identification document when coming to a healthcare institution, a private practice, an organization unit of a health-related higher education institution that performs healthcare activities and other legal entitites which performs certain healthcare activities (Article 40. par. 1). A healthcare institution, private practice and legal entities are obliged to prominently state the name, surname and working hours of the patient counsellor, as well as the address and phone number which the patient can address to protect their rights (Article 40, par 3).

In practice, it has been noticed that the "physical displacement" of the counsellor for patient rights from healthcare institutions has brought about certain difficulties in exercising patient rights, above all in terms of counsellor's availability to patients. Allowing the competent local self-government authorities to decide for themselves whether a patient rights counsellor will perform tasks in one or more local government units further complicates the position of patient counsellors. In the case where one counsellor is in charge of healthcare institutions in more than one local self-government, adequate capacities should be provided, i.e. that the work is not performed by one person. Because of this, counsellors are often unable to provide patients with a report within the statutory time limit (five days for report preparation, three days for report submission).[43] In this way, patients' access to a patient counsellor is restricted, making it difficult

[39] Article 187 of the Statute of the Serbian Medical Chamber, "Official Gazette of the Republic of Serbia", No. 111/2006, 68/2008, 14/2010, 36/2011 – decision of the Constitutional Court, 43/2011, 22/2012 and 70/2017 – decision of the Constitutional Court.

[40] Article 218 of the Statute of the Serbian Medical Chamber.

[41] The procedure of addressing the Ombudsman is available here:< https://www.ombudsman.rs/index.php/prituzba >, accessed 3.01.2020.

[42] Article 38 of the Law on Patient Rights, "Official Gazette of the Republic of Serbia", No. 45/2013 and 25/2019 – state law.

[43] Article 41, par. 2 and 3 of the Law on Patient Rights.

to exercise the rights guaranteed by law. Furthermore, in order to establish the work of patient counsellors and the Health Council, considerable material resources need to be provided at the local self-government level. The fact is that, depending on the financial status of local self-government units, the position of patient counsellors is not the same, which is one of the problems that the competent authorities will have to deal with, because in the light of the chronic economic crisis in Serbia, municipal budgets frequently cannot provide funds for a dignified work of patient counsellors.

Upon the complaint of a patient or their legal representative, a patient counselor shall immediately, and not later than within five working days of the filing of the complaint, investigate all relevant circumstances and facts regarding the allegations made in the complaint. After determining all the relevant facts and circumstances, the patient counsellor composes a report, which is immediately and not later than within three working days, submitted to the complainant, the head of the organizational unit and the director of the healthcare institution or the founder of the private practice. Upon receipt of the report, the director of the healthcare institution, or the founder of the private practice, is obliged to submit to the counsellor a notification of the procedure and the measures taken regarding the complaint within five working days of receiving the report of the patient counsellor (Article 41, paragraph 4). The law stipulates that the director of a healthcare institution, that is, the founder of a private practice, who does not submit within a specified period a notification to a patient counsellor about the measures taken to tackle a complaint (in connection with Article 41, paragraph 4) shall be fined. In practice, there is no data regarding whether this sanctioning mechanism is being implemented.

The Law on Patient Rights stipulates the formation of a Health Council that has certain competences in the procedure of patient rights protection, and Article 15 of the Law on Public Health[44] extends the competences and membership structure of the Health Council. The Health Council plays a major role in the protection of patient rights. It can be regarded as a corrective to a counsellor's decisions as a second instance in decision-making, even though the Law on Patient Rights does not clearly envisage two instances. However, according to the rules of the legal science, this procedure implements the norms of general administrative procedure, so there is no other conclusion than that the Health Council is a second instance authority. Therefore, a complainant dissatisfied with a patient counsellor's report may, in line with the law, address the Health Council. However, confusion arises from the continuation of the provision that states that a patient may simultaneously address the health inspection and the competent authority of the health insurance organization in which the patient is insured (Article 41, paragraph 5).[45] By interpreting the provision, it is concluded that a patient may file an appeal against the counsellor's report with various authorities that act and make decisions independently. This opens a new question: what the protection will be like if the authorities make different decisions. We particularly point to the fact that no article in the law specifies a deadline for filing an appeal, nor do counsellor reports involve a legal remedy that contains all the elements. The second issue arises in the work of the Health Council when it comes to a decision whether patient rights were breached or not. The role of the Health Council as an advisory body, remains unclear if the finality of its decision in an administrative procedure is taken into account. A question remains open as to whether it can serve as an efficient control body for exercising patient rights. First, there is the question of the Health Council's competence to consider patient complaints

[44] Law on Public Health, "Official Gazette of the Republic og Serbia, No. 15/2016".

[45] Article 41, par. 5 of the Law on Patient Rights, "Official Gazette of the Republic of Serbia", No. 45/2013 and 25/2019 – state law.

considering that it is not specified how many lawyers need to be members of this authority. Second, the Council considers complaints, and then informs the complainant and the director of the healthcare institution, or the founder of the private practice targeted by the complaint of the established facts, providing appropriate recommendations. Again, the legal force of these recommendations and their implementation is unclear. From the above, it can be concluded that the recommendations of the Health Council are not a sufficient measure of protection of patient rights, since they are not accompanied by the threat of appropriate sanction for the offender of the patient rights. The only positive solution is that representatives of patient associations are included in the work of the Health Council because it can strengthen their role in health policy-making.

2. Control of Work of Healthcare Institutions

Through its bodies, the Ministry of Health may play a very important role in the protection of healthcare law. Citizens may address the Ministry of Health to complain about the breaches of healthcare regulations, but also to report corruption. However, the authorities acting on citizens' reports play the most important role in healthcare quality assurance, adhering to procedures when securing access to healthcare services, controlling the maintenance of medical records and other obligations related to the functioning of healthcare institutions. The Law on Healthcare provides for two types of quality assurance of professional work – internal and external quality assurance of professional work.[46] Internal quality assurance of professional work is conducted in all healthcare institutions and can be: regular, carried out on the basis of and annual program of quality assurance of professional work; but also an extraordinary one, carried out at the request of the director of a healthcare institution, an expert council, a committee for the improvement of quality of healthcare (the founder of a private practice) and a health / pharmaceutical inspector. This type of control is conducted by a committee for extraordinary internal quality assurance of professional work appointed by the director of a health institution. The Commission for an extraordinary internal quality assurance of professional work shall, within five working days from the day of the request submission, submit a report on the conducted control to the applicant and the director of the healthcare institution. The report must contain information on the established facts, perceived deficiencies and oversights, an expert opinion on the consequences for the patient's health and suggestions for eliminating the observed deficiencies and oversights. The director of the healthcare institution is obliged to consider the report within five working days and act on the proposals for the elimination of the identified deficiencies and oversights.[47]
The Ministry of Health is also competent to conduct an external quality assurance of professional work which may be:

1. Regular and organized based on an annual plan passed by the Minister at the proposal of the institute for public health and the competent chamber of healthcare professionals;
2. Extraordinary, conducted by the Ministry of Health. According to the Law on Healthcare, citizens may submit a request for external quality assurance of professional work of a healthcare institution to the Ministry of Health.[48] Upon receiving the request, the republic expert committee provides an opinion based on which the Ministry considers whether the request is justified. The Ministry shall notify the applicant of its decision within 20 working days. The decision made by the Minister is final and an administrative dispute

[46] Article 188 of the Law on Healthcare, "Official Gazette of the Republic of Serbia ", No. 25/2019.
[47] Article 189 of the Law on Healthcare.
[48] Article 191.par.4. of the Law on Healthcare.

can be initiated against it. The period within which the control must be carried out is no more than 30 days from the date on which the applicant is informed that the control will be carried out.[49]

In order to carry out external quality assurance of professional work, it is necessary to determine the list of professional supervisors proposed to the minister by the competent chamber. Supervisors are obliged to submit the report to the Minister, the health institution and the applicant within ten working days of the completion of the control. The report must include the facts, perceived shortcomings and oversights in professional work, expert opinion on the possible consequences for the health of the patients, as well as tips on how to remedy the perceived shortcomings.

When it comes to legal remedies for a supervisor's report, patients appear to be deprived of legal remedies because only a healthcare institution and a healthcare professional / associate can submit comments to the Minister within five working days of the submission of the report.[50] Therefore, it can be justified to question how effective this safeguard is in protecting patients' rights. In any case, the Minister is reviewing the report of the supervisor and may pass a decision which:[51]

1. prohibits a healthcare institution or private practice to conduct healthcare activities;
2. completely or partially prohibits an organization part of a healthcare institution, another legal entity or private practice to conduct healthacre activities;
3. completely or partially prohibits an organization part of a healthcare institution, another legal entity or private practice to conduct certain healthacre activities;
4. advises the competent chamber to initiate a disciplinary proceeding against a healthcare professional under the conditions provided by this law.

Furthermore, in line with Article 18 of the Law on Inspection Control[52], every citizen may file a complaint with the healthcare inspection. Healthcare inspectors are competent to control the work of a healthcare institution in the sense of the fulfillment of conditions for initiating work and performing healthcare activities in terms of: space, equipment, staff, medications, medical devices. If a healthcare inspector establishes that a healthcare institution failed to comply with the law, they can issue any of a number of meaures, from preventative measures[53] to measures for removing the perceived illegalites and harmful effects and complying with the prescribed obligations of the healthcare institution;[54] also, if they perceive that the controlled entity pursues an illegality punihable by law or another regulation, the inspector can press criminal charges with the competent judiciary authority, as well as charges for economic offense, or a request to intitate criminal proceedings, or they can file a misdemeanor report; or take other actions and measures that the law or another regulation authorizes them to take (like initiating a temporary or permanent license revocation).[55]

All the explained procedures that can be considered as safeguards by regulations, are not in the least harmonized in practice, particularly when addressing a healthcare inspection and submitting a request to initiate an external quality assurance of professional work. Based on the norms, it

[49] Article 191.par.9. of the Law on Healthcare.
[50] Article 193 par. 4 of the Law on Healthcare.
[51] Article194 of the Law on Healthcare.
[52] Law on Inspection Control, "Official Gazette of the Republic of Serbia", No. 36/2015 and 44/2018 – state law and 95/2018. and Article 41, par.5 of the Law on Patient Rights.
[53] Article 26 Law on Inspection Control.
[54] Article 27 Law on Inspection Control.
[55] Article 42 Law on Inspection Control.

can be concluded that these are two completely separate authorities, but when an external quality assurance request is made, the health inspection is always contacted and the report is obtained through them. Due to the above, citizens can easily think that they have already addressed the health inspection and thus fail to use one means of protection.

3. Courts of Honour at Medical Chambers

In Serbia, members of the Serbian Medical Chamber are involved in disciplinary proceedings in courts of honor if, by an act or failure to act, they violate a professional duty or reputation of a Chamber member. The disciplinary responsibility of a doctor – a Chamber member - is determined, not the rights, obligations and legal interests of the parties. Disciplinary proceedings are conducted in the first instance before the courts of honor of regional medical chambers, and in the second instance before the Court of Honor of the Serbian Medical Chamber. Our legislator bases the disciplinary responsibility of the Serbian Medical Chamber members on the principle of enumeration. According to the applicable regulations, the violation of professional duty or reputation of a Chamber member implies one of these actions:

1. acting contrary to the provisions of the law governing healthcare and regulating health insurance in the provision of healthcare services to patients;
2. breaching code of ethics;
3. performing healthcare activities unprofessionally, i.e. contrary to the contemporary achievements of medical, dental or pharmaceutical science and practice, or by making a professional error;
4. treating patients, other chamber members or third persons in a way that harms the reputation of the profession;
5. misusing the health insurance funds while conducting healthcare activities;
6. failing to comply with the obligations of a chamber member, prescribed by law, statute or another general act of the chamber;
7. failing to act on the requirements of the chamber authorities when performing activities within their jurisdiction.[56]

Serbia's legal regulations do not explicitly divide professional offenses into light and serious ones, but they do so indirectly by determining which measures can be imposed for lighter ones, and which for more severe violations of professional duty and the reputation of a Serbian Medical Chamber member.[57] The rules of procedure have elements of administrative and criminal proceeding, and the sanctions affect doctors themselves and are only imposed on individual doctors and not medical institutions. This practically means that by acting in the process of providing healthcare services, a healthcare professional's action can cause one or more, or even all of the listed types of responsibility, and so for a single action, a doctor can be held responsible on one or more grounds at a time.

[56] Article 40, Law on Chambers of Healthcare Professionals and Article 47 of the Serbian Medical Chamber Statute, "Official Gazette of the Republic of Serbia ", No. 111/2006, 68/2008, 14/2010, 36/2011 – a Constitutional Court decision, 43/2011, 22/2012 and 70/2017 - a Constitutional Court decision.

[57] Article 44 of the Law on Chambers of Healthcare Professionals and Article 204 of the Serbian Medical Chamber Statute.

In the Serbian law, the Serbian Medical Chamber is also authorized to conduct a proceeding for revoking a license for independent work (in further text: license).[58] The proceeding is conducted under the conditions provided by the law regulating healthcare, and the chamber director is authorized to pass a decision of license revocation. The proceedings are conducted by courts of honour based on the principles of court proceedings and in line with the principles of general administrative proceedings. License is a public document proving the professional competence of a healthcare professional to perform healthcare activities independently in the Republic of Serbia and may be temporarily or permanently revoked for a doctor, member of the chamber. According to the Law on Healthcare, a license may be temporarily revoked for a period of 6 months to 5 years when a healthcare professional: fails to renew the license to work under the conditions prescribed by law; performs activities for which they have not been licensed; makes a professional error while performing activities, which causes harm to or deteriorates a patient's health; severely violates professional duty and reputation of a chamber member, in accordance with the law and the chamber statute, in which case they may penalized with one of the measures of temporary prohibition of independent work by a competent chamber authority; is convicted by a final judgement, for an offense which renders them unworthy of pursuing their profession; misuses health insurance funds; in other cases prescribed by law.[59]

For violation of professional duty or reputation of a chamber member, depending on the severity of the violation and its consequences, the court of honor may impose disciplinary measures, as follows: public reprimand, a fine of up to 20% of the average monthly salary per employee in the Republic, in the month that precedes the month in which the sentence is pronounced, according to the data of the republican authority responsible for statistics; temporary prohibition of independent work in performing certain health care activities; temporary prohibition of independent work in performing health care activities.[60]

4. Mediation

Article 44 of the Serbian Medical Chamber Statute[61] prescribes mediation for out-of-court settlement of disputes between Chamber members, as well as between a Chamber member and patients, in relation to the performance of healthcare activities, but also that a mediation procedure is to be initiated at the request of disputing parties. The role of mediator is played by the Mediation Commission at the level of regional chambers. The Mediation Commission consists of three members (chair and two members), and it is elected by the Assembly of all regional medical chambers. The members of the Commission perform the tasks under their jurisdiction on the basis of the Rules of Procedure of the Mediation Commission adopted by the Assembly of the Serbian Medical Chamber, as part of its Statute.[62] Members of the Mediation Commission must be trained in conducting the mediation process. The mediation procedure ends with a settlement, that is, the agreement of the parties to the dispute or the finding that the mediation has failed. However, very few patients opt for mediation.

[58] Article 22 of the Serbian Medical Chamber Statute .
[59] Article 185 of the Law on Healthcare.
[60] Article 48 of the Serbian Medical Chamber Statute.
[61] Article 44 of the Serbian Medical Chamber Statute.
[62] Article 175 of the Serbian Medical Chamber Statute.

5. Civil Law Control

Civil law protection through the institute of damage compensation for a medical error is not very popular in Serbia yet, even though globally it represents an efficient and most frequently used legal remedy against medical errors. This is practically the only way for persons who have been harmed by such errors to obtain adequate material satisfaction, which criminal proceedings against doctors cannot provide them. Civil proceedings for compensation for medical errors are conducted before a civil court and represent the most effective legal remedy for damaged patients, as they may result in just satisfaction in the field of property law. The sanction is always material and affects the property of the defendant. The plaintiff is the damaged party, either the patients themselves or their close relatives, in the event that the patient has died as a result of a medical error. Both a doctor and a healthcare institution where they work appear as defendants and are liable jointly for damages. A doctor is liable on the basis of guilt, and a healthcare institution on the basis of liability for another prescribed by Article 171 of the Law on Obligations.[63] Success in a damage compensation proceeding requires the existence of a harmful action, damage and a link between them. It is important to underline that the burden of proving the existence of damage, and the link between a harmful action and damage always lies on the damaged person, as the person claiming to have suffered the damage. The domestic courts have taken the view that the burden of proving a medical error in the narrow sense, ie. the fact that the damage to the plaintiff was caused by the *contra legem artis* medical professional's treatment of the plaintiff. However, there are also positions that in this case there is a shift of the burden of proof from the plaintiff to the defendant, who during the procedure must prove that the medical professional acted in everything in line with the rules of the profession, and that the damage for the plaintiff was not caused by the error of the defendant.[64]

Damage compensation litigations for violating the right to information or consent that is prescribed by the Law on Patient Rights, as the right to the information they need to agree or disagree to a certain medical procedure, are much more frequent and mostly end up unfavourably for the defendant, by adopting a claim for damages.[65] The reason for this is both in the rules on the burden of proof in this case which lies with the respondent, as well as the unwillingness of medical professionals to take seriously their obligation to inform the patient in a timely and appropriate manner about important issues related to the medical method they will apply to them and the possible harmful the consequences that may arise from it. The reason for this is both in the rules on the burden of proof which in this case lies with the defendant, as well as the unwillingness of medical professionals to take seriously their obligation to inform the patient in a timely and appropriate manner about important issues related to the medical method they intend to apply to them and the possible harmful consequences that may arise from it.

6. Criminal Law Control

Criminal proceedings are also pending against an individual's doctor for any of the offenses prescribed by the criminal legislation pertaining to medical activity. This procedure is enforced by the courts, and only the defendants are affected by the sanctions, while civil law sanctions in

[63] Law on Obligations, "Official Gazette of the SFRY ", No. 29/78, 39/85, 45/89 – a decision of the Constitutional Court of Yugoslavia and 57/89, "Official Gazette of the FRY ", no. 31/93 and "Official Gazette of Serbia&Montenegro ", No. 1/2003 – the Constitutional Charter.

[64] Jelena Simić, *Lekarska greška, Građanska odgovornost zbog lekarske greške*, (Službeni glasnik i Pravni fakultet Univerzitet Union, Beograd, 2018), p.213. onward.

[65] Articles 11 and 15 of the Law on Patient Rights.

the form of compensation for material and non-material damage are rarely imposed, although the criminal court is empowered to do so. The Criminal Code of the Republic of Serbia prescribes several criminal offenses that can be charged to medical professionals, both in the section of criminal offenses against life and body, and through a separate section of criminal offenses against human health.[66] Thus, our criminal legislation prescribes the following criminal offenses:

1) *Unauthorized termination of pregnancy*[67]
2) *Failure to act upon healthcare regulations during an epidemic*[68]
3) *Transmitting an infectuous disease*[69]
4) *Transmitting HIV infection*[70]
5) *Unconscientious provision of medical help*[71]
6) *Unlawful conduct of medical experiments and drug testing*[72]
7) *Failure to provide medical help*[73]
8) *Quackery and pharmaceutical quackery*[74]

The law envisages lighter and more serious forms of these offenses and prescribes prison sentences and fines for them. Criminal law control is exercised through these criminal acts, but it is limited in scope and affects first and foremost doctors, providing moral satisfaction, rather than complete satisfaction of the damaged party.

V. CONCLUSIONS

Procedures for the legal control of medical activity and protection of patient rights are still relatively rare in Serbia. However, this is not a reason to be calm, but on the contrary, to think carefully. Frequent headlines in the daily press informs us that our medical service does not function well, that patients are dissatisfied with the healthcare services provided, and that they often suspect medical errors occur in treatment. If these errors are rarely answered for, it means our patients' legal awareness is low or they do not dare to seek judicial protection because they do not believe in the success of litigation, are afraid of obstacles that are difficult to overcome on that path.

When it comes to judicial protection, experience has shown that plaintiffs are, as a rule, disappointed with the court's negative decisions about medical error and guilt. Our judges do not have the necessary knowledge of medical law, which is why their decisions are dictated by medical experts, who give vague answers when asked about a possible medical error. Courts are unable to prevent biased expert testimonies because they do not know how to ask the expert specific and clear questions, to which they would have to provide concrete and clear answers.

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[66] Criminal Code, "Official Gazette of the Republic of Serbia ", No. 85/2005, 88/2005 - corr., 107/2005 - corr., 72/2009, 111/2009, 121/2012, 104/2013, 108/2014, 94/2016 and 35/2019.

[67] Article 120 of the Criminal Code.

[68] Article 248 of the Criminal Code.

[69] Article 249 of the Criminal Code.

[70] Article 250 of the Criminal Code.

[71] Article 251 of the Criminal Code "A doctor who, when providing medical help, applies a manifestly inappropriate remedy or manifestly inappropriate treatment, or fails to apply appropriate hygiene measures, or acts generally unconscientiously, thereby causing a deterioration of a person's health, shall be punished by imprisonment for a term between three months and three years."

[72] Article 252 of the Criminal Code.

[73] Article 253 of the Criminal Code.

[74] Article 254 of the Criminal Code.

When it comes to out-of-court safeguards, patients are often unaware of their existence, or disappointed with the poor functioning of the listed control mechanisms of healthcare professionals' work. They are disappointed that, for example, a counsellor for the protection of patient rights or a health council do not even exist in all local self-government units, so they do not have anyone in their place of residence to complain about the work of a healthcare professional; or patient counsellors themselves are usually not even able to assist patients because their competences are limited, and therefore the patients who suffered damage are in most cases referred to an inspection of the Ministry of Health, which, as a rule, does not respond within the prescribed time limits to the patients' requests, or does not respond at all, and thus again patients remain deprived of legal protection.

In general, it can be said that although there is a wide variety of control mechanisms for the medical sector, patients are still dissatisfied and do not use them, either at all, or very rarely. However, one of the main goals of the legal control of the medical sector is to prevent future errors. It is therefore necessary to constantly work to improve communication between doctors and other medical staff as well as to improve doctor-patient relationships. It is necessary to educate doctors not only on the subject of medical innovations, but also regarding patient rights and how to treat patients. However, the most important thing is to re-teach doctors how to listen to the patient and talk to them.

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