Review article

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MEDICAL LAW AND HEALTH LAW – IS IT THE SAME?

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This is a review of literature on the current position of medical and health law in the legal system of the Republic of Serbia and the world in general. The article defines the similarities and differences of medical and health law with respect to forensic medicine, as well as the similarities and differences between medical and health law, from the point of view of practical, clinical application and possible ethical dilemmas. The reviewed literature suggests that the knowledge of these facts can be crucial for the improvement and full implementation of medical and health law in the legal and health system with the aim of ensuring the quality of health services and exercising the rights of all participants in their provision. On the other hand, full knowledge and application of these branches of law in the field of healthcare activity would additionally contribute to the humanization of legal science.

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Definition of medical and health law

Development of medicine requires development of law branch, known as medical law, which will ensure the quality and rights of all participants in medical service system. Beside the term of medical law there is wider term – health law (1). While the medical law covers an area of regulations relating to the medical operations, the industry operators, the procedures involved in the medical operations, characteristics of medical experts performing medical operations, as well as the relations that occurred while performing medical activities, the health law regulates a wide area of activities, not only medical activities, but also the procedures that are being implemented, the need and necessity of the procedure, professionals who carry out the procedure (1,2). The medical law also covers regulative of drugs and other medical devices. Health law covers a wide area of regulations concerning health, procedural matters and organization of the public health system. From the everyday practice the medical law finds its utility in relation to patients' health, such as: life, body integrity, health, self-determination, as well as personal dignity (2,3).

The review of literature suggests that there are opened questions about similarities and differences of medical and health law especially from the practical implementations, both in law practice and medical industry. The recognized similarities might be as followed: medical law is the branch of law which concerns the prerogatives and responsibilities of medical professionals and the patients, health law is the federal, state, and local law, rules, regulations and other jurisprudence among providers, payers and vendors to the health care industry and its patients; and delivery of health care services; all with an emphasis on operations, regulatory and transactional legal issues (4). On the other side there are some clear differences. Thus, medical law concerns system of medical industry, qualifications of those that provide medical service and their relations to the repaint of medical care. Health care is a wider discipline that concerns all legal acts to human health. This discipline covers the area of procedures, patients, doctors, informed consent and fact that matters to human health (5).

Position of medical law has been elevated to the highest positions, by the European law system implemented by each state, EU members and Council of Europe members. International sources of medical law are the European Convention of Human Rights, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (6). On the contrary, the current position of medical law in Serbia is not so good. It is at the very beginning in Serbian law system, adjusting to the EU Directives. The

Serbian sources of Medical and Health law are the Constitution (Gazette of RS", no. 98/2006), Law on Health care ("Gazette of RS", no. 107/2005, 72/2009 - Law, 88/2010, 99/2010, 57/2011, 119/2012, 45/2013 - Law 93/2014, 96/2015 and 106/2015); Law on Health Insurance ("Gazette of RS", no. 107/2005, 109/2005 - corr., 57/2011, 110/2012 - decision, 119/2012, 99/2014, 123/2014, 126/2014 - decision, 106/2015 and 10/2016), Law on Organ Transplantation ("Gazette of RS", no. 72/2009) etc (7), as well as the series of health law highlights through the history, as it is specified in Table 1 and Table 2 (8).

Table 1. Basic characteristics of medical and health law

BASIC CHARACTERISTICS	
Medical law	**Heath law**
Medical law covers an area of regulations relating to the medical operations, the industry operators, the procedures involved in the medical operations, characteristics of medical experts performing medical operations, as well as the relations that occurred while performing medical activities. the health law regulates a wide area of activities, not only medical activities, but also the procedures that are being implemented, the need and necessity of the procedure, professionals who carry out the procedure, regulative of drugs and other medical devices **M**edical law finds its utility in relation to patients' health, such as: life, body integrity, health, self-determination, as well as personal dignity	**H**ealth law regulates a wide area of activities, not only medical activities, but also the procedures that are being implemented, the need and necessity of the procedure, professionals who carry out the procedure, covers a wide area of regulations concerning health, procedural matters and organization of the public health system. **H**ealth care is a wider discipline that concerns all legal acts to human health. **C**overs the area of procedures, patients, doctors, informed consent and fact that matters to human health.

Table 2. The key Health Law Highlights through the history

Year	Event
1767.	Slater v. Baker and Stapleton, CB Eng Rptr (UK) (medical experimentation)
1803.	Percival's Medical Ethics published (original title, Medical Jurisprudence)
1809.	Commonwealth v. Thompson, 6 Mass. 134 (wrongful death, quackery)
1818.	First medical licensure statute enacted in Massachusetts
1823.	Theodoric Beck's Elements of Medical Jurisprudence published
1840.	Medical malpractice litigation appears in the United States
1860.	John J. Elwell's A Medico-Legal Treatise published
1905.	Jacobson v. Massachusetts, 197 U.S. 11 (no right to refuse smallpox vaccination)
1946–1947.	Doctors' Trial at Nuremberg (Nuremberg Code set forth in the judgment)
1955.	American College of Legal Medicine founded
1966.	Medicare and Medicaid enacted
1972.	American Society of Law and Medicine founded
1973.	Roe v. Wade, 410 U.S. 113 (right to terminate pregnancy)
1990.	Cruzan v. Director, Missouri Department of Health, 497 U.S. 261 (right to refuse life-sustaining treatment)
1997.	Washington v. Glucksberg, 521 U.S. 702, and Vacco v. Quill, 521 U.S. 793 (no right to physician-assisted suicide)
2010.	Patient Protection and Affordable Care Act enacted
2012.	National Federation of Independent Business v. Sebelius (upheld all of the Patient Protection and Affordable Care Act as constitutional except the penalty for states that do not expand their Medicaid programs)

Table 3. Timeline of Major Milestones in Global Health Law Development

Year	Regulatives	
1892.	Adoption of the International Sanitary Convention (predecessor to the International Health Regulations)	Historical predecessors to contemporary WHO instruments
1893.	Adoption of the International List of Causes of Death (predecessor to the International Classification of Diseases)	
1948.	Adoption of Nomenclature with Respect to Diseases and Causes of Death	WHO treaties: Conventions or Regulations
1951.	Adoption of the International Sanitary Regulations (predecessor to the International Health Regulations)	
1955.	Launch of the global program to eradicate malaria	WHO Global Campaigns cosponsored with partners
1959.	Launch of the global program to eradicate smallpox	
1978.	Adoption of the Declaration of Alma-Ata ("Health for All") by the International Conference on Primary Health Care	
1981.	Adoption of the International Code of Marketing of Breast-Milk Substitutes	WHO Nonbinding Normative Instruments
1988.	Launch of the global program to eradicate polio	WHO Global Campaigns cosponsored with partners
1999.	Launch of Vision 2020, a global initiative to eliminate avoidable blindness by the year 2020	WHO Nonbinding Normative Instruments
2000.	Adoption of the Millennium Declaration and Millennium Development Goals	U.N. Nonbinding Resolutions and Declarations
2001.	Publication of the Global Strategy for Containment of Antimicrobial Resistance Adoption of the Declaration of Commitment on HIV/AIDS	WHO Nonbinding Normative Instruments U.N. Nonbinding Resolutions and Declarations
2003.	Adoption of the Framework Convention on Tobacco Control Launch of the 3 by 5 Initiative (HIV treatment for 3 million patients by 2005)	WHO treaties: Conventions or Regulations WHO Global Campaigns cosponsored with partners
2004.	Adoption of the Global Strategy on Diet, Physical Activity, and Health	WHO Nonbinding Normative Instruments
2005.	Adoption of the Revised International Health Regulations	WHO treaties: Conventions or Regulations
2006.	Adoption of the Political Declaration on HIV/AIDS (5-yr follow-up) Launch of the Stop TB Strategy	WHO Nonbinding Normative Instruments U.N. Nonbinding Resolutions and Declarations
2009.	Adoption of the Global Action Plan for the Prevention and Control of Noncommunicable Diseases	WHO Nonbinding Normative Instruments
2010.	Adoption of the Global Code of Practice on the International Recruitment of Health Personnel Adoption of the Global Strategy to Reduce the Harmful Use of Alcohol	
2011.	Launch of the Pandemic Influenza Preparedness Framework Adoption of the Political Declaration on the Prevention and Control of Noncommunicable Diseases • Adoption of the Political Declaration on HIV/AIDS (10-yr follow-up)	WHO Nonbinding Normative Instruments U.N. Nonbinding Resolutions and Declarations
2012.	Adoption of a resolution promoting universal health coverage worldwide	U.N. Nonbinding Resolutions and Declarations
2013.	Launch of the Mental Health Action Plan	WHO Nonbinding Normative Instruments
2014.	Adoption of the Sustainable Development Goals	U.N. Nonbinding Resolutions and Declarations

Law and clinical implications

Medical law regulative contributes precise definition of legal rules that define the medical industry, service providers, and the rights of doctors and patients in the health system. Health law implies the broader term regulations concerning human health. The regulation governs procedures and relationships concerning human health. All relationships, procedures and their influence are connected to certain rights or legal actions and are related to human health. Developing medical and health law will precisely determine the rights and obligations of the providers of medical care and users of health services (5). Regulations will determinate the precise procedures that take place in health institutions, the conditions for performing the procedure, the staff that will provide this type of service, thereby the ability of jeopardizing the patients' rights would be reduced to a minimum (9).

From this point of view the future of medical and health law will be considered as branch of law to develop in the direction of the precise definition of relations between medical service providers and patients. Precise definition of the relationship will improve the implementation and protection of patients' rights and the rights of doctors and health personnel. Medical procedure, the iuridization of medical procedures, informed consent, consequences and expectations, are areas of health law, which must be precisely regulated for the purpose of exercising and protecting the rights of patients (10).

As the pivotal parameters of medical and health law development (Table 3) (8) the following has been recognized: specificity of medical treat ments, which includes interventions, such as therapeutic procedures (as it has been in the past) and also diagnostic procedures; the medicine is developed as the collective medicine depending on technical science development; human factor and medical profession rules (11).

Implementation of medical and health law, both in medical practice and law practice, we can recognize at, for example, organ transplantation. First of all, a doctor must discuss with their patients about this issue before the need of tissues and organs arise as a part of advance care planning (5, 9-11). Organ donation involves several issues. Of particular concern is to avoid any conflict between medical care of potential donor and needs of potential recipient (11). The care of potential donors must be separated from the care of potential recipients. Potential donor's physician should not be responsible for the care of potential recipient and should not be involved in retrieving the organs and tissues. Another set of issues involves financial incentives to encourage organ donation. The financial incentive must not be support to organ donation, although increasing organ donation is a noble goal this shouldn't be the decisive factor for organ donation, which can bring humans as commodities (11, 12).

Legal, ethical and moral decisions

As the essential in the medical and health law three types of decisions that can be made by doctors are recognized: legal, ethical and moral (13). Legal decisions are decisions where the doctor has no choice at all. Ethical decisions are those that the law leaves to the medical profession to regulate, and thus reflect the corporate morality of the profession. A moral decision is the one which is entirely uninhibited by anything other than the conscience of the individual doctor.

The type of decision that is recognized as a Legal Decision is the one where the law and regulation govern acceptable conduct. Usually it does this when the law recognizes the issues to relate to patients right, and in that way enables the matter to be used as justification for regulating medical conduct. Reflection of this law influence to medicine is the most clarified in the context of informed consent. As a consequence of that influence, and also the influence of court decisions, especially in European law systems, changed the importance of emphasis and prioritization of patients' rights to autonomy, than being based on duties of the doctor as it was considered in the past (12,13). This influence contributed to enhanced recognition of both the ethical aspects of informed consent and patients' autonomy (11-14). The importance of protecting the autonomy is particularly shown in the case of Chester vs. Afshar. This case led to The House of Lords (Great Britain) to declare that if the law does not protect the autonomy, it must be changed. This could not be limited only to informed consent. As an example of importance of patients' autonomy can be found in case of Ms B vs. A in the NHS Trust. Ms B was maintained on ventilator, so she felt her quality of life was so poor that she wanted to die. She asked her doctors to do that thing. Ms B's doctors refused to cease the ventilator, arguing that this kind of decision might be identified as killing her, and it was 'unethical' from their point of view (12-14). She went to court to force the doctors to stop the ventilation. The court applied simple and ground legal rules. Doctor must respect the wishes of patient, in situation when there is a patient with sound mind, and properly informed about procedure, respect the autonomy of patient. Ms B refused to be on ventilator so doctors must cease it. The ventilation ceased and Ms B died. What is of interest to us here is the fact that the medical profession tried to claim the issue of the desirability of Ms. B's survival as its own, by defining it as 'ethical' in nature (15). The court recognized the patients' right of autonomy, therefore forced doctors to cease the ventilator. In this case we can see that the law took the matter with the ethical content and defined it as legal, as it is approached in the paper of Foster and Miola (13, 15).

The type of Professional Medical Ethical decisions are those that the law decides are best resolved by medical profession itself, as it is defined in the

same paper (13-16). But there must be made a distinction: when there are 'ethical' issues involved, it can not be considered that it is the best way to decide by the medical profession. More 'ethical' issues requires the law to take control of making the decision, due to issues other than appropriate performance of medical skills, as it is mentioned in the paper of Foster and Miola (13).

The type of moral decision is the one where it is left to an individual to make a decision, and this type of decision is correctly referred to as being moral in nature. Moral decision must not be harmful for the patient. The rights protected then are related not to the patient but to the doctor (13,16).

In conclusion, medical law is a branch of law covering the wide authorities of medical industry, providers and medical service users, rights of patients and doctors. Health law is a discipline expanding its authorities, which may be wider than that of medical law, concerning the regulations related to human health. Within its scope, a health law regulates the procedures related to human health, binding together basic human rights and legal actions. Based upon the findings presented here, it could be said that there are differences between medical and health law. Although medical and health law are often being perceived separately, these should not be strictly separated, because both of the disciplines contribute to the humanization of law.

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MEDICINSKO I ZDRAVSTVENO PRAVO – DA LI JE ISTO?

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Rad se bavi pregledom literature na temu trenutne pozicije medicinskog i zdravstvenog prava u pravnom sistemu Republike Srbije i u svetu uopšte. U radu se definišu sličnosti i razlike medicinskog i zdravstvenog prava u odnosu na sudsku medicinu, ali i sličnosti i razlike između medicinskog i zdravstvenog prava i to sa stanovišta praktične, kliničke primene i mogućih etičkih nedoumica. Pregledana literature sugeriše da poznavanje ovih činjenica može biti ključno za unapređenje i potpunu implementaciju medicinskog i zdravstvenog prava u pravni i zdravstveni sistem sa ciljem osiguravanja kvaliteta zdravstvene usluge i ostvarivanje prava svih učesnika u njihovom pružanju. S druge strane, potpuno poznavanje i primena ovih grana prava u oblasti zdravstvene delatnosti dodatno bi doprinela humanizaciji pravne nauke.

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Ključne reči: *medicina, pravo*