

**MINISTRY OF EDUCATION AND SCIENCE OF UKRAINE  
NATIONAL UNIVERSITY «UZHHOROD NATIONAL UNIVERSITY»  
FACULTY OF LAW  
DEPARTMENT OF ADMINISTRATIVE, FINANCIAL AND INFORMATIVE LAW**

**MEDICAL LAW**  
(methodological recommendations)

Uzhhorod – 2023

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## INTRODUCTION

The curriculum of the normative academic discipline «Medical Law» is developed based on the educational-professional program of the Ministry of Education and Science of Ukraine for the bachelor's degree in the field of 22 «Health care» specialty 222 «Medicine».

The subject of study of the academic discipline is social relations that arise in the process of medical activities. The purpose of teaching the academic discipline is to acquire knowledge of medical law as a separate branch of legal science.

The course enables students to gain skills in defining the specifics of medical legal relations; medical ethics, deontology, and bioethics; the fundamentals of economic activities and medical insurance in the healthcare system, the procedures and specifics of the contract for the provision of medical care and its types, as well as the legal qualification of medical malpractice.

The main objectives of studying the academic discipline are to acquire theoretical and practical knowledge for its application in professional activities; to cultivate legal culture and legal awareness among students, understanding the tasks and purposes of medical law; to provide students with theoretical knowledge about modern concepts, scientific perspectives, and controversial issues in the field of medical law; to develop legal thinking and the ability to critically assess problematic issues and form well-argued opinions; to study legislative acts, judicial practices, major judgments of the European Court of Human Rights, and draft normative acts, which will contribute to the ability to analyze and interpret norms of medical law and apply them to specific circumstances; and to assimilate contemporary trends in scientific research in Ukraine.

As a result of studying this course, the student should:

To know the conceptual and categorical framework in the field of medical law; the trends in legislation and state policies in the healthcare sector; the mechanisms of exercising rights and duties of subjects in medical legal relations; the legal conditions for conducting various types of medical activities and their legal regulation; the state-legal guarantees and mechanisms for protecting human rights in the healthcare sector; the legal qualification of medical malpractice and its defects; the types of legal liability for violations in the field of healthcare; the legal practice in the field of medical law, including that of the European Court of Human Rights.

To be able to work independently with the legislation of Ukraine and international and regional standards in the healthcare sector; know the mechanisms of exercising rights and duties of subjects in medical legal relations; prepare necessary legal documents; analyze the legal nature of specific types of medical practice; apply legal practice, including the legal positions of the European Court of Human Rights; effectively utilize the arsenal of expertise and mechanisms for quality control of medical care; accurately assess the consequences of professional activities of medical and pharmaceutical workers.

### DESCRIPTION OF THE COURSE

<b>Characteristic</b>	<b>Meaning</b>
Name	Medical Law
Code and name of the field	22 «Health care»
Name of specialty	«Medicine»
Education level	Bachelor
Characteristic	Normative
The course on which it is studied	4
Study semester	7
ECTS Credits	3
Content modules	1
The total number of hours	90
Weekly hours	2

<b>course</b>	<b>semester</b>	<b>classes, hours</b>					<b>the total number of hours</b>	<b>Control: exam/credit</b>	<b>credits</b>
		<b>lectures</b>	<b>consultations</b>	<b>seminars</b>	<b>classroom hours</b>	<b>independent work</b>			
4	7	10		20	30	60	90	credit	3

## STRUCTURE OF THE ACADEMIC COURSE

The topic title	The number of hours				
	total	lectures	consultations	seminars	independent work
Introduction to medical law	10	2	0	2	6
Healthcare institutions, medical personnel and patients	12	4	0	2	6
Medical care and medical services	10	2	0	2	6
Privacy, confidentiality, and informed consent	10	2	0	2	6
Deficiencies in the provision of medical care and iatrogenic pathology	8	0	0	2	6
Family medicine	8	0	0	2	6
Provision of medicinal products and prosthetic devices to the population	8	0	0	2	6
Reproductive technologies, surrogate motherhood and termination of pregnancy	8	0	0	2	6
Anatomical material transplantation	8	0	0	2	6
Euthanasia. Definition of the moment of death of a person	8	0	0	2	6
<b>The total number of hours</b>	<b>90</b>	<b>10</b>	<b>0</b>	<b>20</b>	<b>60</b>

## **LECTURE SCHEDULE**

### **LECTURE 1. INTRODUCTION TO MEDICAL LAW**

1. Medical legal relations: concepts, types, and composition.
2. Grounds for the emergence, modification, and termination of medical legal relations.

### **LECTURE 2. HEALTHCARE INSTITUTIONS, MEDICAL PERSONNEL AND PATIENTS**

1. Legislative provision of patients' rights: international and national standards.
2. Regulatory regulation of patients' obligations.
3. Legal regulation of rights of medical personnel.
4. Legal regulation of professional duties of medical personnel.
5. Legal status of a treating physician according to national legislation.

### **LECTURE 3. MEDICAL CARE AND MEDICAL SERVICES**

1. Medical service as an object of medical legal relations.
2. Types of medical services.
3. General characteristics of the contract for the provision of medical services and its main features.
4. Composition of parties and content of the contract for the provision of medical services.

### **LECTURE 4. PRIVACY, CONFIDENTIALITY, AND INFORMED CONSENT**

1. Medical confidentiality as an object of legal regulation.
2. Entities responsible for preserving medical confidentiality.
3. Legality of disclosure of medical confidentiality.
4. Informed consent of the patient regarding the provision of medical care: concepts and types.
5. Conditions (criteria) for the lawfulness of informed consent.
6. Forms of expression and methods of documenting informed consent.
7. Performance of medical intervention without patient consent. Refusal of medical intervention.

## PRACTICAL SCHEDULE

### SEMINAR 1. INTRODUCTION TO MEDICAL LAW

1. Medical legal relations: concepts, types, and composition.
2. Grounds for the emergence, modification, and termination of medical legal relations.

#### *Tasks for students:*

1. Determine which legal acts regulate relations in the field of health care in Ukraine.

#### *Recommended reading:*

1. Alekseeva I. M., Alekseev A. G., Anischenko M. A. Workshop for practical lessons and independent work of students of the Faculty of International, speciality "Medicine". P. 6-8. URL: <http://bitly.ws/LQUu>
2. Gostin L. O., Taylor A. L. Global Health Law: A Definition and Grand Challenges. *Public Health Ethics*. Vol. 1. Is. 1. April 2008. P. 53–63.
3. Todorovski N. Medical law and health law – is it the same? *Acta Medica Medianae*. 2018. Vol. 57 (2). P. 34-39.

### SEMINAR 2. HEALTHCARE INSTITUTIONS, MEDICAL PERSONNEL AND PATIENTS

1. Legislative provision of patients' rights: international and national standards.
2. Regulatory regulation of patients' obligations.
3. Legal regulation of rights of medical personnel.
4. Legal regulation of professional duties of medical personnel.
5. Legal status of a treating physician according to national legislation.

#### *Tasks for students:*

1. Define the rights and responsibilities of medical workers.
2. What are the ethical limitations in the practice of a doctor according to Ethical Code of the Doctor of Ukraine?

#### *Recommended reading:*

1. Baulin Yu., Rohozhyn B., Vyshnevskaya I. Legal regulation of professional obligations of physicians in Ukraine. *Wiadomości Lekarskie*. 2019. T. LXXII. Nr. 9. Cz II. P. 1839-1843.
2. Vilchik T., Sokolova A. Areas for further improvement of legislative regulation of patients' rights in Ukraine. *Wiadomości Lekarskie*. 2019. T. LXXII. Nr 7. P. 1324-1330.

### SEMINAR 3. MEDICAL CARE AND MEDICAL SERVICES

1. Medical service as an object of medical legal relations.
2. Types of medical services.
3. General characteristics of the contract for the provision of medical services and its main features.
4. Composition of parties and content of the contract for the provision of medical services.

#### *Tasks for students:*

1. Determine the main elements of a contract for the provision of medical services.

#### *Recommended reading:*

1. Buletsa S., Deshko L., Zaborovskyy V. The Peculiarities of Changing Health Care System in Ukraine. *Med Law*. 2019. № 38. P. 427.
2. Chen Yi, et al. Blockchain-based medical records secure storage and medical service framework. *Journal of medical systems*. 2019. № 43. P. 1-9.
3. Jaffe E., et al. Evolution of emergency medical calls during a pandemic—An emergency medical service during the COVID-19 outbreak. *The American journal of emergency medicine*. 2021. № 43. P. 260-266.

#### **SEMINAR 4. PRIVACY, CONFIDENTIALITY, AND INFORMED CONSENT**

1. Medical confidentiality as an object of legal regulation.
2. Entities responsible for preserving medical confidentiality.
3. Legality of disclosure of medical confidentiality.
4. Informed consent of the patient regarding the provision of medical care: concepts and types.
5. Conditions (criteria) for the lawfulness of informed consent.
6. Forms of expression and methods of documenting informed consent.
7. Performance of medical intervention without patient consent. Refusal of medical intervention.

##### ***Tasks for students:***

1. What actions should a doctor take to prevent disclosure of medical secrets?
2. Complete the patient's informed consent.

##### ***Recommended reading:***

1. Bani I. W., et al. Privacy, confidentiality, security and patient safety concerns about electronic health records. *International nursing review*. 2020. № 67.2. P. 218-230.
2. Cohen I. G. Informed consent and medical artificial intelligence: What to tell the patient? *Geo. LJ*. 2019. № 108. P 1425.
3. Showalter J. S. *The Law of Healthcare Administration*. 9<sup>th</sup> edition. Chicago, Illinois: Health Administration Press; Washington, DC: Association of University Programs in Health Administration. 663 p.

#### **SEMINAR 5. DEFICIENCIES IN THE PROVISION OF MEDICAL CARE AND IATROGENIC PATHOLOGY**

1. Deficiencies in the provision of medical care: concepts and criteria for classification.
2. Legal assessment of adverse treatment outcomes for patients.
3. Characteristics of deficiencies in the pre-hospital period, outpatient period, and inpatient treatment.
4. Medical error and adverse event.
5. Concept and main causes of iatrogenesis: subjective and objective factors, their prevention.
6. Classification of iatrogenic conditions. The role of iatrogenic pathology in adverse treatment outcomes.

##### ***Tasks for students:***

1. Is there a difference between defects in the provision of medical care and iatrogenic pathologies?

##### ***Recommended reading:***

1. Anderson J. G., Abrahamson K. Your Health Care May Kill You: Medical Errors. *Stud Health Technol Inform.* 2017. URL: <https://pubmed.ncbi.nlm.nih.gov/28186008/>.
2. Czochra M., Bar D. Śmierć pacjenta wywołana zastosowaniem sztucznej inteligencji w technologiach medycznych–analiza prawnokarna. *Studia Prawnicze: rozprawy i materiały.* 2019. № 2 (25) C. 67-81.
3. Soroka O. Błędy medyczne–doświadczenia ukraińskie. *Kortowski Przegląd Prawniczy.* 2022. № 1. C. 31-36.

#### **SEMINAR 6. FAMILY MEDICINE**

1. General characteristics of family medicine: concepts, principles, significance, and international standards.
2. Legislative support for family medicine in Ukraine.
3. Legal status of a family physician.

#### ***Tasks for students:***

1. Make a diagram on the topic: "How to conclude a declaration with a family doctor?"

#### ***Recommended reading:***

1. Iunes R. Who should pay for the continuity of post-trial health care treatments? / R. Iunes, M.V. Uribe, J.B. Torres [et al.]. *International Journal for Equity in Health.* 2019. Vol. 18, No. 1. Article number 26.
2. Kolisnykova H. V. Legal nature of contract for provision of state medical services. *Journal of Advanced Research in Law and Economics.* 2019. Vol. 10, No. 7. P. 2032-2034.

#### **SEMINAR 7. PROVISION OF MEDICINAL PRODUCTS AND PROSTHETIC DEVICES TO THE POPULATION**

1. Creation, manufacturing, and marketing of medicinal products: legal aspects.
2. Patenting of medicinal products.
3. Concept and legal framework of generic medicinal products.
4. State control of the quality of medicinal products in Ukraine.
5. Provision of prosthetic assistance.

#### ***Tasks for students:***

1. What a doctor must be able to write an electronic prescription?

#### ***Recommended reading:***

1. Iglesias-Lopez C., et al. Regulatory framework for advanced therapy medicinal products in Europe and United States. *Frontiers in pharmacology.* 2019. № 10. P. 921.
2. Kostytsky V., Suhodolska A. Правове регулювання забезпечення лікарськими засобами в умовах війни (теоретико-правовий огляд). *Scientific works of National Aviation University. Series: Law Journal Air and Space Law.* № 4 (65) C. 51-58.
3. Shah A., Marks P. W., Hahn S. M. Unwavering regulatory safeguards for COVID-19 vaccines. *Jama.* 2020. № 10 (324). P. 931-932.
4. Shtuchna N. I., Vyshnevskya L. I. Досвід роботи екстемпоральної аптеки та забезпечення населення ліками в умовах воєнного стану. *News of Pharmacy.* 2022. № 2 (104) C. 54-60.

#### **SEMINAR 8. REPRODUCTIVE TECHNOLOGIES, SURROGATE MOTHERHOOD AND TERMINATION OF PREGNANCY**



1. Concept of assisted reproductive technologies and their types.
2. Legal foundations of reproductive cell donation.
3. Legal regulation of *in vitro* fertilization procedure.
4. Surrogacy: concept, conditions, and legal foundations.
5. Surrogacy agreement: features and liability for breaches.
6. Specifics of applying surrogacy for foreigners.
7. Voluntary artificial termination of pregnancy.

**Tasks for students:**

1. What are the legal grounds for abortion?

**Recommended reading:**

1. Boldizhar S., Pishta V. ECHR Position on Transplantology and Reproductive Rights: Main Aspects. *Studia Iuridica. Cassoviensia*. Univerzita Pavla Jozefa Šafárika v Košiciach. Právnická fakulta. ISSN 1339-3995, 2017. Ročník 5. Číslo 2. P. 25-34.
2. Jahr F. A Panorama of the Human Being's Ethical Relations with Animals and Plants (Translated by Jose Roberto Goldim). URL: <https://www.ufrgs.br/bioetica/jahreng.pdf>

**SEMINAR 9. ANATOMICAL MATERIAL TRANSPLANTATION**

1. Donor, recipient, and transplant coordinator.
2. State information systems for transplantation.
3. Relationship between the concepts of "presumed consent" and "presumed dissent."
4. Right to physical integrity of an individual.
5. Posthumous donation. Specifics of obtaining consent.

**Tasks for students:**

1. Who can be a donor of anatomical materials in Ukraine?

**Recommended reading:**

1. Boldizhar S., Pishta V. ECHR Position on Transplantology and Reproductive Rights: Main Aspects. *Studia Iuridica. Cassoviensia*. Univerzita Pavla Jozefa Šafárika v Košiciach. Právnická fakulta. ISSN 1339-3995, ročník 5. 2017, číslo 2. P. 25-34.
2. Opt-out organ donation: pros and cons. *The Week Day Newsletter*: website. URL: <https://www.theweek.co.uk/35635/automatic-organ-donation-the-pros-and-cons>

**SEMINAR 10. EUTHANASIA. DEFINITION OF THE MOMENT OF DEATH OF A PERSON**

1. Right to die as a legal category.
2. Definition, features, and types of euthanasia.
3. Procedure for exercising the right to euthanasia.
4. Determination of irreversible death of a person and cessation of active measures to sustain a patient's life.

**Tasks for students:**

1. Watch one of the suggested movies: «The Sea Inside» (2004), «You Do not Know Jack» (2010).

**Recommended reading:**

1. Colombian Constitutional Court Decision № C-239-97. URL: <https://www.corteconstitucional.gov.co/english/Decision.php?IdPublicacion=9214>.

2. End of Life Option Act. June 9, 2016. URL: [https://leginfo.legislature.ca.gov/faces/codes\\_displayText.xhtml?lawCode=HSC&division=1.&title=&part=1.85.&chapter=&article=](https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=1.&title=&part=1.85.&chapter=&article=)

3. Hayashi M., Kitamura T. Euthanasia trials in Japan: Implications for legal and medical practice. *International Journal of Law and Psychiatry*. 2002. Vol. 25. P. 563.

4. Kai K. Euthanasia and Death with Dignity in Japanese Law. *Waseda Bulletin of Comparative*

5. Voluntary Assisted Dying Act 2017. № 61 of 2017. URL: [https://content.legislation.vic.gov.au/sites/default/files/8caaf3b4-28f6-3ad1-acf3-e3c46177594e\\_17-61aa003%20authorised.pdf](https://content.legislation.vic.gov.au/sites/default/files/8caaf3b4-28f6-3ad1-acf3-e3c46177594e_17-61aa003%20authorised.pdf).

6. Wet toetsing levensbeëindiging op verzoek en hulp bij zelfdoding, 12 april 2001. URL: <https://wetten.overheid.nl/BWBR0012410/2020-03-19>.

### **THE TOPICS FOR STUDENTS' WORK:**

1. Historical development of medical law.
2. Bioethics, biolaw, and medical law: issues of correlation.
3. Right to healthcare.
4. Limitations of citizens' rights related to their health status.
5. Legal status of individual entrepreneurs as economic entities in the healthcare sector.
6. Formation of healthcare policies in Ukraine.
7. State supervision and control in the healthcare sector.
8. System of standards in the healthcare sector.
9. Models of healthcare system organization: national and international experience.
10. Emergence and development of modern technologies in healthcare.
11. Electronic healthcare system.
12. Insurance of medical and pharmaceutical professionals working in specific areas of medical practice.
13. Prevention of infectious diseases hazardous to the population.
14. Specialized medical care.
15. Legal regulation of palliative care.
16. Organizational and legal functioning of hospices.
17. Obligation to provide medical information.
18. Medical-biological experiments on humans.
19. Blood donation and its components.
20. Application of sterilization methods.
21. Gender reassignment (correction) procedures.
22. Prevention and treatment of rare (orphan) diseases.
23. Legal regulation of cosmetology and sports recreational activities (sports medicine).

## **AN APPROXIMATE LIST OF QUESTIONS FOR THE FINAL ASSESSMENT:**

1. Concept, subject, and methods of medical law.
2. Principles and functions of medical law.
3. Medical law as a science and academic discipline.
4. Concept and main types of sources of medical law. System of medical law.
5. Concept, types, and components of medical legal relations.
6. Role and significance of medical ethics and deontology in the overall structure of social regulation of medical activity.
7. International legal standards in healthcare.
8. Constitutional regulation of healthcare in Ukraine.
9. General characteristics of national legislation in healthcare (historical and legal overview).
10. Legislative support for healthcare in Ukraine: current state and development prospects.
11. Systematization of Ukrainian legislation on healthcare.
12. Bioethics, biolaw, and medical law: issues of correlation.
13. Healthcare institutions in Ukraine as economic entities.
14. Licensing and accreditation of healthcare institutions.
15. Emergence and development of modern technologies in healthcare: national and international experience.
16. General provisions on insurance in the healthcare sector: concepts, principles, subjects, objects, and content of insurance legal relations.
17. Voluntary medical insurance.
18. Insurance against industrial accidents and occupational diseases causing disability.
19. Concept and characteristics of medical assistance (qualitative, qualified, accessible, free).
20. Right to medical assistance according to Ukrainian legislation.
21. Concept and characteristics of subjects of medical law.
22. Patient: definitional and classification approach.
23. Concept and general characteristics of the patient's legal status.
24. Patient's rights in specific areas of medical activity.
25. Medical worker and their legal status.
26. Legislative support and classification of the rights of medical workers.
27. General organizational and legal issues, criteria for legality, and forms of informed consent.
28. Concept and types of procedures and mechanisms for protecting the rights of subjects of medical legal relations: concepts, types, means of implementation.
29. International forms and means of protecting the rights of subjects of medical legal relations.
30. Concept and types of legal liability of subjects of medical legal relations.
31. Definition of medical confidentiality.
32. Regulatory and legal framework for maintaining medical confidentiality.
33. Subjects of maintaining and the object of medical confidentiality.
34. Legality of disclosing medical confidentiality.
35. Legal regulation of medical expertise.
36. Forensic medical and forensic psychiatric expertise.
37. Military medical and alternative expertise.
38. Types and procedures for providing psychiatric care.
39. Problems of artificial insemination and surrogate motherhood.
40. Legal regulation of medical genetics.

41. Ethical and legal issues of cloning.
42. Legal bases of bioethics: problems of expert activity in protecting patients' rights.
43. Pathoanatomical examination.
44. Legal qualification of defects in medical care.
45. Medical error and accident.
46. Iatrogenic pathology: relevance and main causes of occurrence.
47. Civil legal liability in the field of medical care and services.
48. Disciplinary liability of medical workers.
49. Administrative liability of medical workers for offenses in healthcare.
50. Criminal liability of healthcare system workers.
51. Legal liability of patients.
52. Role of pharmaceutical workers in providing medical care.
53. State policy on the circulation of medicinal products in Ukraine.
54. Creation and production of medicinal products: legal aspects.

## THE MAIN CRITERIA FOR ASSESSING STUDENTS' KNOWLEDGE

The evaluation of students' knowledge, skills, and practical abilities in the academic discipline "Medical Law" is carried out according to the schedule provided in the table.

Throughout the year, students study 1 content module. After completing this module (lectures, practical sessions), ongoing assessment is conducted in the form of written, oral work, or testing. The evaluation of students' learning achievements and practical skills is done using a 100-point grading system for the content module.

A student who scores more than 60 points in ongoing assessment (during testing, written work, or quizzes) or in the final assessment of the module has the right not to take the final exam for the discipline. If a student receives a passing grade for the module, they also have the option to waive taking the final exam. In this case, the overall final grade is recorded in the academic record. However, if the student wants to improve their final grade for the module, they must take the final exam.

A student who scores less than 60 points in the final assessment of the module is required to take the final exam for the discipline. If the student's answers during the exam are evaluated with less than 60 points, they will receive an unsatisfactory final grade. In this case, the results of ongoing assessments are not considered.

<b>Number of points per course</b>	
Current assessment	40
Evaluation of the modular task	60
<b>SEMESTER TEST (CREDIT)</b>	<b>100</b>

The sum of points for all types of educational activities	ECTS	Evaluation on a national scale	
		for an exam, course project (work), practice	for credit
90 – 100	<b>A</b>	excellent	passed
82-89	<b>B</b>	good	
74-81	<b>C</b>		
64-73	<b>D</b>	satisfactory	
60-63	<b>E</b>		
35-59	<b>FX</b>	fail, with the possibility of reassembly	fail, with the possibility of reassembly
0-34	<b>F</b>	fail, with mandatory repeated study of the discipline	fail, with mandatory repeated study of the discipline