

**Danylo Halytskyi Lviv National Medical University**

Department of Medical Law of the Faculty of Post-Graduate Education

“Approved”  
By Acting First vice-rector  
on scientific-pedagogical work  
ass. prof. I.I. Solonyenko

\_\_\_\_\_ 2023  
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**WORKING PROGRAM**

**OF THE ACADEMIC DISCIPLINE  
“MEDICAL LAW”**

**on the preparation of the second (master) educational level professionals**

Branch of knowledge: 22 “Health care”  
Specialization: 221 “Dentistry”

Discussed and adopted on the meeting of the Department _____, _____ 2023 Minutes No. ___ of _____ Head of the Department, professor I. Y. Senyuta _____ signature	Approved by the profile methodic commission _____, _____ 2023 Minutes No. ___ of _____ Head of the commission, dean of the FPGE, associate professor O. Y. Sichkoriz _____ signature
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2023

## INTRODUCTION

**The program of study of the discipline "Medical Law " is compiled in accordance with the Standard of Higher Education of Ukraine (hereinafter - the Standard) for the second (master's) level of the field of knowledge 22 "Health care", specialty 221 "Dentistry".**

### **Description of the discipline (abstract)**

Medical law as an academic discipline is not a new phenomenon in medical education, because it were medical institutions that first began to introduce this course into the curricula of students and trainees at the undergraduate and postgraduate levels, which was then picked up by law schools of higher education in Ukraine. Our country is in the midst of fundamental changes in all areas of government, including health care. The political and legal conditions of the medical reform, with the adoption of the Resolution of the Cabinet of Ministers of Ukraine "On Approval of the Regulation on the System of Continuing Professional Development of Medical and Pharmaceutical Workers", provide for many changes in the medical education system, as well as thorough organizational, managerial, and personnel transformations in this area with a human rights orientation. And this, of course, creates the need to train specialists who will be able to respond adequately and effectively to the transformation processes, which are framed by the law.

The updated curriculum, which takes into account the challenges of today, is designed to provide students with the necessary knowledge and skills to make their future practice as smooth as possible. Laying the foundation for legal knowledge from the student's bench will help to form the legal consciousness and legal culture of future professionals, which will contribute to building harmonious doctor-patient relationships.

Structure educational disciplines	Number of hours, with them			Year teaching	Type of control	
	In total	classrooms				SRS
		Lectur es	Practical occupation			
Name of discipline: "Medical law" <i>Content modules</i> <i>I</i>	45 hours, Credits ECTS-1.5	10	10	25	3rd	test

**The subject of the discipline** is to provide theoretical knowledge and develop skills in the practical application of the law, to help students develop a high level of legal awareness and legal culture, and to prevent legal nihilism.

**Interdisciplinary connections.** The discipline "Medical Law" is a necessary component in the competency-based approach to the formation of a doctor who must understand the spectrum of the health care system, know the national regulatory framework, the basics of law in medicine, and, if necessary, correctly apply the knowledge gained in practice. The study of the discipline is related to the knowledge of social, humanitarian and natural science disciplines that students study throughout their studies.

The program for the discipline "Medical Law" for higher medical education institutions is compiled in the field of knowledge 22 "Health care", specialty 221 "Dentistry". The discipline is studied in the 3rd year of study.

The program of the discipline is structured and consists of one module, which, in turn, contains three content blocks.

## **1. Purpose and objectives of the discipline**

1.1. The purpose of studying the discipline is the professional training of students majoring in "Dentistry" in order to form and develop their competence in the field of medical law, aimed at obtaining the necessary amount of theoretical medical and legal knowledge, acquiring practical skills in the field of health care, mastering a sufficient level of legal culture and legal awareness to maintain a balance of relations between the subjects of medical legal relations and respect for human rights in the field of health care.

1.2. The main objectives of the discipline are to provide students with knowledge, in particular, on the history of the legal regulation of medical activities in Ukraine; constitutional regulation of human rights in the field of health care in Ukraine; general and special legislation in the field of health care; types of legal liability for professional offenses in this area; rights and obligations of subjects of medical legal relations (patients, health care workers, legal representatives of the patient, etc.); defects in the provision of medical care; and

1.3. Competencies and learning outcomes that the discipline contributes to (relationship with the normative content of higher education training formulated in terms of learning outcomes in the Standard).

According to the requirements of the Standard, the discipline ensures that students acquire competencies:

- **general:**

1. Ability to abstract thinking, analysis and synthesis.
2. Ability to apply knowledge in practical situations.
3. Knowledge and understanding of the subject area and understanding of professional activities.

4. Ability to conduct research at the appropriate level.

5. Ability to learn and master modern knowledge.

6. Ability to identify, pose and solve problems.

- **special** (professional, subject) knowledge of:

1. conceptual and categorical apparatus in the field of medical law;

2. sources of medical law; trends in rulemaking and state policy in the field of health care;

3. mechanisms for exercising the rights and obligations of subjects of medical legal relations;

4. legal conditions for certain types of medical practice and their legal regulation;

5. state legal guarantees and mechanisms for the protection of human rights in the field of health care;

6. defects in the provision of medical care, their legal qualification;

7. types of legal liability for offenses in the field of health care;

8. legal practice in the field of medical law, including the European Court of Human Rights.

**Be able to:**

- work independently with the legislation of Ukraine and international and regional standards in the field of health care;

- know the mechanisms for exercising the rights and obligations of subjects of medical legal relations

- prepare the necessary legal documents;

- analyze the legal nature of dental and other types of medical practice;

- apply legal practice for law enforcement activities, including legal positions of the European Court of Human Rights;

- effectively use the arsenal of expertise and mechanisms for quality control of medical care;

- correctly assess the consequences of the professional activities of medical and pharmaceutical workers.

**Develop practical skills:**

- exercise their rights and obligations;
- protect their rights and legitimate interests;
- work with the legislation of Ukraine and search for the necessary legal norms;
- verbally and in writing, logically correctly justify legal phenomena and processes;
- work with the texts of the main regulatory acts, in particular the Constitution of Ukraine, the Civil Code of Ukraine, the Labor Code of Ukraine, the Code of Administrative Offenses of Ukraine, the Criminal Code of Ukraine the Law of Ukraine "Fundamentals of Legislation of Ukraine on Health Care".

Detailing competencies in accordance to descriptors NRK in form "Matrix competencies".

**Matrix of competences**

No	Competence	Knowledge	Skill	Communication	Autonomy and responsibility
<i>General competences</i>					
ZK 1	Ability to abstract thinking and analysis	To know the current trends in the development of the industry and the indicators characterizing them	Be able to analyze professional information, make informed decisions, acquire modern knowledge	Establish appropriate connections to achieve goals.	To be responsible for the timely acquisition of knowledge.
ZK 2	Ability and understanding of the subject area of the profession	To know the peculiarities of the professional activity of a dentist	To be able to carry out professional activities that require updating and integration of knowledge	Form a communication strategy in professional activities	Be responsible for continuous development with a high level of autonomy
ZK 3	Ability to apply knowledge in practical activities	Know the methods of implementing knowledge in solving practical tasks	Be able to use professional knowledge to solve practical problems	To establish connections with subjects of practical activity	Be responsible for the validity of the decisions made
ZK 4	Ability to communicate in the national language both orally and in writing	Know the state language, including the professional direction	To be able to use the state one for carrying out professional activities and communication	Form a communication strategy in professional activities	Be responsible for continuous professional development with a high level of autonomy
ZK 5	Ability to communicate in	Possess a foreign language at a level	Be able to use a foreign	Form a communication	Be responsible for continuous

	English.	sufficient for professional communication	language for professional activities and communication	strategy in professional activities	professional development with a high level of autonomy
ZK 6	Skills in using information and communication technologies	Have the necessary knowledge about the use of information and communication technologies	Be able to use information and communication technologies	Use information and communication technologies	To be responsible for the use of information and communication technologies

### The results teaching:

Integrative final abilities, formed by academic discipline.

Know your social and public rights and responsibilities. Form your civil consciousness, to be able to act in accordance with it. The ability to convey one's public and social position Answer for your own civil position and activity.

### The results of studying the discipline

Know the responsibilities and ways of performing assigned tasks. Be able to determine the purpose and task be persistent and conscientious at implementation responsibilities Establish interpersonal relationships for effective performance of tasks and duties. To be responsible for quality performance of delivered tasks

### Program learning outcomes

PRN-1. To organize medical and evacuation measures among the population, military personnel, in emergency situations, including martial law, during the expanded stages of medical evacuation, taking into account the existing system of medical evacuation support.

PRN-2. To form goals and determine the structure of personal activity based on the result of the analysis of certain social and personal needs.

PRN-3. Follow a healthy lifestyle, use self-regulation and self-control techniques.

PRN-4. To be aware of and be guided in one's activities by civil rights, freedoms and duties, to raise the general educational cultural level.

PRN-5. Analyze and evaluate government, social and medical information using standard approaches and computer information technologies.

PRN-5. To comply with the requirements of ethics, bioethics and deontology in their professional activities.

### Correspondence of learning outcomes and competencies defined by the standard

Result of teaching	Program result code of teaching	Code of competencies
To organize medical and evacuation measures among the population, military personnel, in emergency situations, including martial law, during the expanded stages of medical evacuation, taking into account the existing system of medical evacuation support.	<i>PRN-1</i>	<i>ZK-1, ZK-2, ZK-3, ZK-4, ZK-5, ZK-6</i>
To form goals and determine the structure of personal activity based on the result of the analysis of certain social and personal needs.	<i>PRN-2</i>	<i>ZK-1, ZK-2, ZK-3, ZK-4, ZK-6</i>

Follow a healthy lifestyle, use self-regulation and self-control techniques.	PRN-3	ZK-1, ZK-2, ZK-3, ZK-4, ZK-5,
To be aware of and be guided in one's activities by civil rights, freedoms and duties, to raise the general educational cultural level.	PRN-4	ZK-1, ZK-2, ZK-3, ZK-4, ZK-5, ZK-6
Analyze and evaluate government, social and medical information using standard approaches and computer information technologies.	PRN-5	ZK-1, ZK-2, ZK-3, ZK-4, ZK-5, ZK-6
To comply with the requirements of ethics, bioethics and deontology in their professional activities.	PRN-6	ZK-1, ZK-2, ZK-3, ZK-4, ZK-5, ZK-6

**Informative amount educational disciplines on study educational disciplines is assigned 1.5 credits ECTS, 45 hours**

## **Content module 1**

### **Medical Law as a Legal Phenomenon**

#### **Objective of the content module 1**

- As a result of studying of content module 1, students should know the conceptual-categorical apparatus in the field of medical law; types of sources of medical law; trends of rule-making and public policy in the health sector; foundations of economic activity in the area of insurance and health care; legal nature of health care and medical services; characteristics of medical services contract.

#### ***Topic 1. Medical law in the system of law and system of legislation***

Legal nature of medical law (branch of law, institute of law, branch of legislation). Place of medical law in the system of law and system of legislation.

Medical Law of Ukraine as a branch of law: concept, objectives, subject matter and methods. Medico-legal relations: concept, types and composition.

Principles and functions of medical law of Ukraine.

System of medical law of Ukraine.

Sources of medical law of Ukraine.

Medical law as an academic discipline and field of science.

#### ***Topic 2. International standards in the field of health care and human rights***

International standards in the field of health care and human rights: general characteristics.

International acts in the field of health care and human rights which contain binding rules and principles ("hard law") (including International Covenant on Civil and Political Rights, International Covenant on Economic, Social and Cultural Rights, Convention on the Rights of the Child, Convention on the Rights of Persons with Disabilities).

International acts in the field of health care and human rights, which contain recommendation standards and principles ("soft law") (e.g., Standard Minimum Rules for the Treatment of Prisoners, Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care, Alma-Ata Declaration, Lisbon Declaration on the Rights of the Patient).

The role and importance of the Universal Declaration of Human Rights and its place in the international standards in the field of health care and human rights.

Patients' rights under the international standards of human rights in patient care.

Health professionals' rights under the international standards of human rights in patient care.

### ***Topic 3. Regional standards in the field of health care and human rights***

Regional standards in the sphere of health care and human rights: general characteristics.

Regional acts in the field of health and human rights that contain binding rules and principles ("hard law") (including Convention for the Protection of Human Rights and Fundamental Freedoms, European Social Charter, Convention on I human Rights and Biomedicine).

Regional acts in the field of health and human rights that contain recommendation standards and principles ("soft law") (including European Charter of Patients' Rights, Declaration on the Promotion of Patient Rights in Europe, Ljubljana Charter on Reforming Health Care in Europe).•

Patients' rights under the regional standards of human rights inpatient care.

Health professionals' rights under the regional standards of human rights in patient care.

The place and importance of the European Court of Human Rights judgments in the field of health care and human rights.

### ***Topic 4. Legal regulation of the health care system in Ukraine***

Genesis of the health care system's legal regulation in Ukraine.

Legislation of Ukraine on healthcare: current state and development prospects.

Constitutional regulation of healthcare in Ukraine

Branch legislation of Ukraine in the field of health care.

Ukraine-EU Association Agreement in the field of health care.

The role and importance of the European Court of Human Rights in the health care sector.  
Domestic jurisprudence in medical cases.

## **Content module 2**

### **Legal Status of Medico-Legal Relations Subjects and Mechanisms of their Rights Protection**

#### **Objective of the content module 2**

- As a result of studying content module 2, students should know the rights and duties of medico-legal relations participants, in particular those of key ones: patient and medical professional, general characteristic of defects of medical care, as well as concepts, types and procedure of bringing health professionals to legal responsibility.

### ***Topic 5. The system of human rights in patient care. Personal non property rights***

Human rights in patient care: concept, classification, general characteristics.

The right to life and medical practice: the issues of correlation.

Human right to health care.

Human right to medical care. The right to consent and refusal of medical intervention.

Human right to medical information: general characteristics and legal regulation.

Human right to medical confidentiality: general characteristics and legal regulation.

Human rights of a person, who receives in-patient treatment.

The procedure for the processing of personal data in the health care sector.

### ***Topic 6. Legal status of medico-legal relations participants***

Legal regulation of patient rights, international standards and national laws. Patient rights in certain types of medical practice.

Legal regulation of patient responsibilities in Ukraine.

Legal regulation of medical professionals professional rights.

Legal regulation of medical professionals professional responsibilities.

Legal status of the legal representatives and other medico-legal relations participants.

Legal status of the doctor in charge under national law.  
Professional ethics and medical deontology in the course of carrying out medical practice.

***Topic 7. Defects of medical care. Medical examination and control over the quality of medical care under the legislation of Ukraine***

Defects of medical care: the concept and types.  
Legal assessment of the defects of medical care.  
Legal regulation of expert's activity in Ukraine.  
Concept, types and importance of medical examinations in Ukraine. The expert's conclusion. Legal regulation of quality control of medical care.  
Conditions and procedure for monitoring the quality of medical care.

***Topic 8. Legal liability in the field of health care. Procedures and mechanisms for the rights protection of medico-legal relations participants***

Concept and types of legal liability of medico-legal relations participants. Exemption from legal liability: legal grounds.  
Criminal liability of medical professionals for committing professional crimes. Civil liability in the field of health care.  
Administrative liability of medical professionals.  
Disciplinary liability of medical professionals.  
The concept and types of forms of rights of medico-legal relations participants protection.  
Judicial form of medico-legal relations participants rights protection.  
Non-judicial form of medico-legal relations participants rights protection.  
Non-jurisdictional forms of medico-legal relations participants rights protection: self-defense; alternative dispute resolution; applying for help to independent NGOs; applying to professional medical associations.

### **Content module 3**

#### **Legal Regulation of Certain Types of Medical Activity**

##### **Objective of the content module 3**

- As a result of studying content module 3 students should know the general characteristics and legal conditions for carrying out certain types of medical activity and legal regulation thereof.

***Topic 9. Legal regulation of carrying out dental practice in Ukraine***

Dental care in Ukraine: legal regulation.  
Legal status of patients in the field of dentistry.  
Legal status of medical professionals in the field of dentistry.  
Legal assessment of the adverse effects of dental care.  
Medical and legal standards of dental care organization and provision.  
Features of dental tourism legal regulation.

***Topic 10. Legal regulation of family medicine in Ukraine.***

General characteristics of family medicine: concepts, principles, values and international standards.  
Legal regulation of family medicine in Ukraine.  
Legal status of general practice clinic - family medicine.  
Legal status of the family doctor.  
Medical and social activity of family doctor: legal aspects.



***Topic 11. Legal regulation of prophylactics and treatment of infectious diseases. Legal regulation of sanitary and epidemiological welfare in Ukraine***

General characteristics of legal regulation in the field of health care concerning protection of the population against infectious diseases.

Legal status of medico-legal relations participants in the course of infectious and sexually-transmitted diseases treatment.

Fighting tuberculosis: legal aspects.

Peculiarities of social and legal protection of persons infected with HIV or persons, who are suffering from a disease caused by HIV.

General characteristics of legal regulation of functioning of State service of Ukraine on safety of foods and protection of consumers.

Rights and responsibilities of citizens as regards to the provision of sanitary and epidemiological welfare.

Legal liability for the violations of sanitary legislation.

***Topic 12. Legal regulation of donation in Ukraine***

Concept and types of donation under the laws of Ukraine.

Legal regulation of organization and carrying out donation blood and its components: international legal standards and national legislation.

Features of legal regulation of organ and other anatomic materials donation.

Features of the legal regime of reproductive cells donation.

***Topic 13. Legal regulation of carrying out pharmaceutical activity and providing the population with medicines and medical equipment in Ukraine. Intellectual property in the field of health care***

Legal regulation of pharmaceutical activity in Ukraine. The concept and legal status of pharmaceutical professionals.

Carrying out pharmaceutical practice. Advertising of medicines.

Legal liability of pharmaceutical professionals for professional crimes.

General characteristics of legislation in the field of providing medical drugs to the population. Creation, producing and sale of medicines: legal aspects.

Patenting medicines.

Concept and legal regime of generic medicines. The grounds and procedure for issuing a compulsory license for a patent, the object of which is a medical drug.

State quality control of medicines in Ukraine.

Legal guarantees for the provision of drugs and medical equipment to certain categories of people in Ukraine.

***Topic 14. Legal regulation of providing medical care to the vulnerable groups of the population***

Legal regulation of carrying out special measures aimed at prevention of chronic alcoholism, drug addiction and other socially dangerous diseases. State policy on tobacco control in Ukraine.

Specifics of realizing children's rights in the sphere of patient care.

Legal regulation of medical care to the disabled persons provision.

Regulatory support of medical to imprisoned persons provision.

Legal regulation of medical care to the elderly persons provision.

***Topic 15. Legal regulation of palliative care. Legal organization of hospices functioning in Ukraine***

General characteristics of palliative care legal regulation in Ukraine.

International legal standards in the field of palliative care.

Procedure of providing medical care.  
 Organizational and legal bases of creation and functioning of palliative care facilities.  
 Legal status of the person who is provided with palliative care in Ukraine.  
 Legal status of medical professional, who is providing palliative care.

**Structure of the educational discipline  
 "Medical Law"**

No	Topic	Lectures	Practical classes	SRW
<b>Content module 1. Medical Law as a Legal Phenomenon</b>		<b>6</b>	<b>4</b>	<b>6</b>
1.	Medical law in the system of law and system of legislation	1	1	1
2.	International standards in the field of health care and human rights	1	1	1
3.	Regional standards in the field of health care and human rights	2	1	2
4.	Legal regulation of the health care system in Ukraine	2	1	2
<b>Content module 2. Legal Status of Medico-Legal Relations Subjects and Mechanisms of their Rights Protection</b>		<b>2</b>	<b>4</b>	<b>8</b>
5.	The system of human rights in patient care. Personal non-proprietary rights	-	-	2
6.	Legal status of medico-legal relations participants	2	2	2
7.	Defects of medical care. Medical examination and control over the quality of medical care under the legislation of Ukraine	-	-	2
8.	Legal liability in the field of health care.	-	2	2
<b>Content module 3. Legal Regulation of Certain Types of Medical Activity</b>		<b>2</b>	<b>2</b>	<b>11</b>
9.	Legal regulation of carrying out dental practice in Ukraine	2	2	1
10.	Legal regulation of family medicine in Ukraine.	-	-	1
11.	Legal regulation of prophylactics and treatment of infectious diseases. Legal regulation of sanitary and epidemiological welfare in Ukraine	-	-	2
12.	Legal regulation of donation in Ukraine	-	-	2
13.	Legal regulation of carrying out pharmaceutical activity and providing the population with medicines and medical equipment in Ukraine. Intellectual property in the field of health care	-	-	2
14.	Legal regulation of providing medical care to the vulnerable groups of the population	-	-	2
15.	Legal regulation of palliative care. Legal organization of hospices functioning in Ukraine	-	-	1
<b>Total</b>		<b>10</b>	<b>10</b>	<b>25</b>

**Thematic plan of the lectures**

No	Topic	Number of hours
1.	Medical law in the system of law and system of legislation. Legal regulation of the health care system in Ukraine	2
2.	International standards in the field of health care and human rights	2
3.	Regional standards in the field of health care and human rights	2
4.	Legal status of medico-legal relations participants	2
5.	Legal regulation of carrying out dental practice in Ukraine	2
<b>Total</b>		<b>10</b>

### Thematic plan of the practical classes

No	Topic	Number of hours
<b>Content module 1. Medical Law as a Legal Phenomenon</b>		<b>4</b>
1.	Medical law in the system of law and system of legislation. Legal regulation of the health care system in Ukraine	2
2.	International and regional standards in the field of health care and human rights	2
<b>Content module 2. Legal Status of Medico-Legal Relations Subjects and Mechanisms of their Rights Protection</b>		<b>4</b>
3.	Legal status of medico-legal relations participants	2
4.	Legal liability in the field of health care. Procedures and mechanisms for the rights protection of medico-legal relations participants	2
<b>Content module 3. Legal Regulation of Certain Types of Medical Activity</b>		<b>2</b>
5.	Legal regulation of carrying out dental practice in Ukraine	2
<b>Total</b>		<b>10</b>

### Self-reliant work of the students and control thereof

No	Topic	SRW	Type of control
<b>Content module 1. Medical Law as a Legal Phenomenon</b>		<b>6</b>	
1.	Medical law in the system of law and system of legislation	1	Current control during practical classes
2.	International standards in the field of health care and human rights	1	
3.	Regional standards in the field of health care and human rights	2	
4.	Legal regulation of the health care system in Ukraine	2	
<b>Content module 2. Legal Status of Medico-Legal Relations Subjects and Mechanisms of their Rights Protection</b>		<b>8</b>	
5.	The system of human rights in patient care. Personal non-proprietary rights	2	Current control during practical classes
6.	Legal status of medico-legal relations participants	2	
7.	Defects of medical care. Medical examination and control over the quality of medical care under the legislation of Ukraine	2	
8.	Legal liability in the field of health care.	2	
<b>Content module 3. Legal Regulation of Certain Types of Medical Activity</b>		<b>11</b>	
9.	Legal regulation of carrying out dental practice in Ukraine	1	
10.	Legal regulation of family medicine in Ukraine.	1	

11.	Legal regulation of prophylactics and treatment of infectious diseases. Legal regulation of sanitary and epidemiological welfare in Ukraine	2	Current control during practical classes
12.	Legal regulation of donation in Ukraine	2	
13.	Legal regulation of carrying out pharmaceutical activity and providing the population with medicines and medical equipment in Ukraine. Intellectual property in the field of health care	2	
14.	Legal regulation of providing medical care to the vulnerable groups of the population	2	
15.	Legal regulation of palliative care. Legal organization of hospices functioning in Ukraine	1	
<b>Total</b>		<b>25</b>	

### **METHODS OF TEACHING**

During classes and self-reliant work, students, under the guidance of the professor, study the concept of medical law, international and regional standards in the field of patient care, the system of human rights, legal status of medico-legal relations participants, defects of medical care, legal liability in the field of health care, legal regulation of certain types of medical activity and work individually by solving tests and situational problems.

Current educational activity of students is supervised during practical classes in accordance with the specific purpose; assessment of students' achievements is evaluated according to rating system and is defined as the system of ECTS, and the traditional four-point scale: "5" - 40 points, "4" - 32 points, "3" - 24 points "2" - 0 points (max - 200 points, min - 120 points on the discipline).

### **METHODS OF CONTROL**

Forms of control and evaluation system are carried out according to the requirements of the Thematic Plan of the discipline and Instruction on the system of evaluation of educational activity of students in credit-modular system of educational process, developed on the basis of a letter to the Ministry of Health Ukraine No. 08.01-22 / 65 as of 21 January 2008.

A mark on the module is defined as the sum of marks of current educational activity (in points), which students receive during practical classes, according to the list defined by the Thematic Plan of the discipline.

The maximum number of points students can get (test credit) is 200 points.

Current control is carried out in each class according to the specific goals of each topic. In assessing students' educational activity preference should be given to the standardized methods of control: solving issues and problems for self-testing, solving situational problems with the conditions that are maximally close to reality, preparing creative tasks.

### **Evaluation of the current educational activity**

Evaluation of current educational activity of students is conducted on a compound basis using standardized methods of students' knowledge on the topic assessment, discussing theoretical material (solving tests, tasks and questions for self-control), and finally the ability of students to apply their knowledge on practice is assessed in the course of solving situation tasks and creative tasks.

The value of each topic within a module must be the same and it is determined by the number of topics in the module. Evaluation of current educational activity of students is described in the Thematic Plan on the discipline.

Individual work of students on each topic of the module is evaluated during current educational activity and students get marks using 4-points traditional scale. The marks, which students receive, are converted into points.

The conversion system of the traditional system of marks into points depends on specific number of days, when practical classes are carried out according to Thematic Plan, which may be different in higher medical educational institutions. A decision is made by the administration of the higher medical educational institution according to binding legal documents, which were adopted in the stabled order.

Assessment of a self-reliant work of students is conducted during current control at the relevant practical classes.

### **Peculiarities of assessment of the discipline in case of implementation the credit final testing as method of control.**

Assessment of studying results of students is conducted with application of traditional marks and ECTS marks.

Assessment is carried out basing on the results of the current study.

Lack of final module control.

Adaptation of the evaluation system to the ECTS system:

200 points: Number of classes = maximum number of points equals mark "5";

Minimum number of points (60% of the maximum points) equals mark "3";

The average number of points between Max. — Min. corresponds to mark "4".

In order to successfully pass the discipline it is necessary to :

- Fulfill the educational program.
- Receive positive marks as a result of current control. Mark "2" and "Absent" should be repassed.
- Receive minimum number of points during educational procedure.
- Inform students about the necessity to receive the highest points, since the results of studying will be ranked according to the ECTS scale. These marks will be put into annex to the diploma.

### **Conversion of points according to the system of ECTS and 4-points (traditional) system**

The number of points, which student receives, is converted into the ECTS scale in the following way

<b>ESTC mark</b>	<b>Statistic data</b>
A	10% of the best students
B	25% of the rest students
C	30% of the rest students
D	25% of the rest students
E	Last 10% of the students

Students, who did not pass the discipline receive the mark FX, F («2»).

Students, who received a mark FX, F («2») after studying the discipline did not fulfill the educational program or did not get the minimum number of points, that is why they need to study a module from the discipline for the second time. Such decision falls into the scope of the administration of the higher medical educational institution competence according to binding legal documents, which were adopted in the established order.

Points from the discipline, which students received after successful fulfillment of the program of the course, are converted into traditional "4-points" scale with taking into account absolute criteria.

<b>Points on the discipline</b>	<b>Mark according to the 4-points scale</b>
170 – 200 points	5

140 – 169 points	4
139 – minimum number of points student shall receive	3
Less than minimum number of points the student can receive	2

### **LIST OF QUESTIONS, NECESSARY FOR THE PREPARATION TO THE DISCIPLINE**

1. Legal nature of medical law (branch of law, institution of law, branch of legislation).
2. Medical Law of Ukraine as a legal phenomenon: concepts, tasks object of legal regulation.
3. Medico-legal relations: concept, types and composition.
4. Principles and functions of medical law of Ukraine.
5. The system of medical law of Ukraine.
6. Sources of medical law of Ukraine.
7. Medical law as an academic discipline and field of science.
8. General characteristics of legal regulation of the health care in Ukraine.
9. International acts in the field of health care and human rights, which contain binding rules and principles ("hard law") (including International Covenant on Civil and Political Rights, International Covenant on Economic, Social and Cultural Rights, Convention on the Rights of the Child, Convention on the Rights of Persons with Disabilities)
10. Regional acts in the field of health care and human rights, which contain binding rules and principles ("hard law") (including European Convention for the Protection of Human Rights and Fundamental Freedoms, European Social Charter, European Convention on Human Rights and Biomedicine).
11. International acts in the field of health care and human rights, that contain nonbinding (recommendatory) standards and principles ("soft law") (e.g., International Standard Rules for the Treatment of Prisoners, Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care, Alma-Ata Declaration, Declaration of Lisbon on Rights of the Patient).
12. Regional acts in the sphere of health care and human rights that contain non-binding (recommendatory) standards and principles ("soft law") (including European Charter of Patients' Rights, Declaration on the Promotion of Patients' Rights in Europe, Ljubljana Charter on Reforming Health Care).
13. The role and importance of the Universal Declaration of Human Rights and its place within the international standards in the sphere of health and human rights.
14. Rights of patients fixed in the international standards in the field of health care and human rights.
15. The rights of medical professionals fixed in the international standards in the field of health care and human rights.
16. Rights of patients under regional standards in the field of health care and human rights.
17. Rights of medical professionals under regional standards in the field of health care and human rights.
18. Place and importance of European Union laws in the system of regional standards of health care and human rights.
19. Ukraine-EU Association Agreement in terms of health care.
20. The constitutional regulation of health care in Ukraine.
21. The role and importance of the European Court of Human Rights judgments, related to health care, in the system of healthcare legislation of Ukraine, and judgments of the domestic courts.
22. Place of medical law in the social regulation of medical practice.
23. The systematization of legislation of Ukraine on health care.

24. Bioethics, medical law and biolaw: Problems of correlation.
25. The role and importance of international and national organizations in the development of medical law.
26. Ukrainian health care facility as a commercial entity.
27. Licensing and accreditation of health care facilities.
28. Advertising in the field of health care.
29. Organizational and legal aspects of records management in health care facilities.
30. Formation and development of new technologies in the field of health care (including telemedicine, cybermedicine, quantum medicine).
31. General provisions on healthcare insurance: concepts, principles of insurance, subject matter, participants, objects and composition of the insurance relationships.
32. Voluntary medical insurance: current status of legal regulation and application.
33. Formation and development of compulsory state social health insurance.
34. Professional insurance of medical professionals' liability.
35. Insurance of medical and pharmaceutical professionals, who perform their professional duties in specific areas of medical practice.
36. The concept and features of medical care (high-quality, qualified and free of charge medical care).
37. The right to health care under the laws of Ukraine.
38. Medical service as an object of medico-legal relationship.
39. Medical services agreement: concept, general characteristics and features of fulfillment.
40. Contractual liability in the field of health care.
41. Human rights in patient care: concepts, classification, general characteristics.
42. Guarantees of human rights in patient care provision.
43. The right to life: concept, content and general characteristics. The right to life and medical practice: the issue of value.
44. The concept and structure of the human right to health care under the laws of Ukraine.
45. The right to medical information: general characteristics and legal regulation.
46. The right to medical confidentiality: general characteristics and legal support.
47. The right to consent to medical intervention.
48. The right to refuse from medical intervention.
49. The procedure of personal data processing in the field of health care.
50. Concept and types of medico-legal relations.
51. Patient: Definitional and classification approaches.
52. General characteristics of the patient.
53. Legal regulation of patient's responsibilities in Ukraine.
54. The moral and ethical principles of "doctor-patient" relations.
55. Features of the legal status of the legal representatives in the field of health care.
56. Medical professional and his/her legal status: conceptual-categorical apparatus and classification.
57. Legal regulation of rights of medical professionals.
58. Legal regulation of professional responsibilities of medical professionals.
59. Legal status of the doctor in charge under the national laws.
60. Concept and types of procedures and mechanisms for the protection of medico-legal relations participants rights.
61. Forms of rights protection in human health relations: concept, types, means of exercise.
62. Judicial form of protection of medico-legal relations participants rights in constitutional and administrative proceedings.

63. Judicial form of protection of medico-legal relations participants rights in civil proceedings.
64. Judicial form of protection of medico-legal relations participants rights in criminal proceedings.
65. Extrajudicial form of protection of medico-legal relations participants rights: concept, types and general characteristics.
66. Violations in the health care sphere as a basis for legal liability in medical law: concept, features, characteristics.
67. The concept and types of legal liability of medico-legal relations participants.
68. Civil liability in the field of health care.
69. Disciplinary liability of medical professionals.
70. Administrative liability in medical law.
71. Criminal liability of medical professionals, connected with their professional activity.
72. Exemption from legal liability of medical professionals.
73. Non-jurisdictional forms of medico-legal relations subjects' protection: concept, types and general characteristics.
74. Execution of court judgments in medical cases.
75. International forms and means of medico-legal relations participants protection.
76. Legal practice in the field of medical law.
77. Features of legal liability of patients under the laws of Ukraine.
78. Expert's activity in the health care sector: national and international legislation.
79. Concept, types and importance of medical examinations in Ukraine.
80. Expert's conclusion: form and content.
81. Medical and social disability examination: the concept and types.
82. Forensic examination: general characteristics and its role in medical law.
83. Forensic psychiatric examination: general characteristics and its role in medical law.
84. Forensic psychological examination: general characteristics and its role in medical law.
85. Military Medical examination: general characteristics and its role in medical law.
86. Alternative medical examination: analysis and its role in medical law.
87. Postmortem examination: peculiarities of carrying out and its role and importance for medical cases.
88. Defects of medical care: the concept and types.
89. Medical error and accident.
90. Iatrogenic disease: topicality and basic causes.
91. Complications of the results of medical interventions and their legal consequences.
92. Control over the quality of medical care: concept, types and entitled persons.
93. Features of clinical expert commissions' operation.
94. Features of legal regulation of dental tourism.
95. Dental care in Ukraine: legal regulation.
96. Legal status of patients in the field of dentistry.
97. Legal status of medical professionals in the field of dentistry.
98. Legal assessment of the adverse effects of the provision of dental care.
99. Medical and legal standards of organization and provision of dental care.
100. Peculiarities of dental practice taxation.
101. Legal regulation of carrying out private dental practice.
102. Commercial activity in the field of dentistry.
103. General characteristics of family medicine: concepts, principles, values and legal regulation.
104. Legal status of clinic of general practice, family medicine.
105. Legal status of the family doctor.
106. Concept and types of donation under the laws of Ukraine.



107. Concept and principles of blood and its components donation.
108. Legal regulation of human organs and other anatomical materials donation.
109. Legal regulation of reproductive cell donation in Ukraine.
110. International and regional standards in the field of health care aimed at population protection from infectious diseases, including sexually transmitted diseases.
111. Legal regulation of prevention and treatment of infectious diseases in Ukraine, including sexually transmitted diseases.
112. Legal status of medico-legal relations participants in terms of treatment of infectious diseases, including sexually transmitted diseases.
113. Legal status of medical and other professionals, whose professional activity is associated with the risk of HIV infection.
114. Features of social and legal protection of persons living with HIV or people suffering from diseases caused by HIV.
115. Legal regulation of preventive vaccinations in Ukraine.
116. Fighting tuberculosis: legal aspects.
117. The concept and legal status of pharmaceutical professionals.
118. The role of pharmaceutical professionals in the course of medical care provision.
119. Carrying out pharmaceutical practice.
120. Advertising of medicines.
121. General characteristics of legislation in the field of providing the population with medicines.
122. The creation and production of medicines: legal aspects.
123. Legal and ethical regulation of clinical trials of drugs.
124. Specifics of state quality control of medicines in Ukraine.
125. Legal guarantees of provision to certain categories of the population in Ukraine with medicines and medical equipment.
126. Pre-clinical study of medicinal products.
127. State policy on narcotic drugs in Ukraine.
128. International and regional standards, and national acts on intellectual property in the field of health care.
129. Patenting of drugs.
130. Concept and legal regime of generic medicines.
131. The grounds and procedure for issuing a compulsory license for a patent, having dug as its object.
132. Legal regime of registration information (registration dossier) of a medical drug.
133. Legal regulation of biomedical experiments in the Ukraine.
134. Legitimate grounds and procedure of biomedical experiments involving humans.
135. Clinical trials on humans.
136. State policy on combating tobacco smoking in Ukraine.
137. Peculiarities of exercising the rights of children in the field of health care.
138. Legal regulation of providing medical care to persons with disabilities in Ukraine.
139. Legal regulation of providing medical care to detained persons.
140. Legal regulation of providing medical care to the elderly persons.

## **LIST OF RECOMMENDED LITERATURE**

### **Basic literature**

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  6. David Orentlicher and Tamara K. Hervey *The Oxford Handbook of Comparative Health Law*: New York. publishing house: Oxford University Press 2021. 1136 Pages
  7. Foley, Elizabeth Price, *The Evolution of Health Care Decision-Making: The Political Paradigm and Beyond* (January 14, 2010). *Tennessee Law Review*, Vol. 65, No. 619, 1998; Florida International University Legal Studies Research Paper No. 10-14. Available at SSRN: <http://ssrn.com/abstract=1536328>
  8. *Health and Human Rights: A Resource Guide*. Available at: <http://fxb.harvard.edu/health-and-human-rights-resource-guide/>
  9. Klick, Jonathan and Stratmann, Thomas, *Medical Malpractice Reform and Physicians in High-Risk Specialties* (January 28, 2010). *Journal of Legal Studies*, Vol. 36, p. S121, 2007. Available at SSRN: <http://ssrn.com/abstract=870492> or <http://dx.doi.org/10.2139/ssrn.453481>
  10. *Law and Ethics in Medical Practice an Overview//* <http://www.fmshk.org/article/746.pdf>
  11. Martinsen, Dorte Sindbjerg and Vasev, Nikolay, *A Difficult Encounter: National Healthcare Models and the European Union* (May 18, 2015). *Social Policy and Administration*, Vol. 49: 4, Forthcoming. Available at SSRN: <http://ssrn.com/abstract=2607553>
  12. Mastaneh, Zahra and Mouseli, Lotfollah, *Patients Awareness of Their Rights: Insight from a Developing Country* (July 11, 2013). *International Journal of Health Policy and Management*, Vol. 1, 2013. Available at SSRN: <http://ssrn.com/abstract=2293270>
  13. Miola, José and Foster, Charles, *Who's in Charge? The Relationship between Medical Law, Medical Ethics and Medical Morality* (November 7, 2014). University of Leicester School of Law Research Paper No. 14-28. Available at SSRN: <http://ssrn.com/abstract=2520488> or <http://dx.doi.org/10.2139/ssrn.2520488>
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  17. P.-L. Chau, *Jonathan Herring Emergent Medicine and the Law* Publisher: Palgrave Macmillan; 2021. 330 pages
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