

**PRIVATE HIGHER EDUCATIONAL ESTABLISHMENT  
«INTERNATIONAL ACADEMY OF ECOLOGY AND MEDICINE»**

**Department of fundamental disciplines with a course of pharmacology**

**SYLLABUS OF THE EDUCATIONAL  
DISCIPLINE**

**" Medical law of Ukraine"**


LEVEL OF HIGHER EDUCATION The second (master's) level

DEGREE OF HIGHER EDUCATION Master

AREA OF KNOWLEDGE 22 "Health care"

SPECIALTY 221 "Dentistry"

Reviewed and approved  
at the meeting of the Department of fundamental  
disciplines with a course of pharmacology

Protocol № 1 of « 01 » 09 2020  
Head of the department Doctor of Biological  
Sciences, associate professor  
                      M.R. Vergolyas

**Kiev 2020**

<b>1. General information</b>	
<b>Subject</b>	Medical law of Ukraine
<b>Lector</b>	Ph.D. K. Varukcha
<b>Teacher's contact phone number</b>	095 737-00-03
<b>Teacher's e-mail</b>	k.varukhasme@gmail.com
<b>Discipline format</b>	Normative discipline.
<b>The volume of the discipline</b>	45 hours
<b>Link to the distance learning site</b>	maem.kiev.ua
<b>Consultations</b>	Tuesday of each week 16.00-17.30
<b>2. Annotation to the course</b>	
<p><b>The subject of study of the discipline:</b> Economic and social and social conditions testify to the necessity of changes in the system of organization of medical and preventive help to the population.</p> <p>There are many problems in the healthcare sector in Ukraine that need immediate resolution:</p> <ul style="list-style-type: none"> <li>- lack of proper legal acts regulating relations related to the provision of medical care;</li> <li>- insufficient knowledge and understanding of the content of legal norms, which reflect the rights of citizens in the field of health care;</li> <li>- poor legal training of healthcare professionals;</li> <li>- low level of legal culture of medical professionals.</li> </ul> <p>In this regard, there was an urgent need to radically change the quality of legal training for students of higher medical institutions. The reform of the health care system in Ukraine depends on a number of factors. Of these, the legal education of future physicians is important.</p>	<p><b>Interdisciplinary links-</b> discipline is based on the study by students of medical biology, normal and pathological physiology, microbiology, medicinal chemistry, pharmacology, clinical disciplines, laboratory and functional diagnostics and integrates with these disciplines.</p>
<b>3. Purpose and objectives of the course</b>	
<p><b>The main tasks of studying the discipline are:</b></p> <ul style="list-style-type: none"> <li>- definition of types of legal liability for offenses in the field of health care; legal practice in the field of medical law, including European Court of Human Rights;</li> <li>- mastering the legal conditions of certain types of medical practice and their legal regulation;</li> <li>- assessment of trends in rule-making and public policy in the field of health care;</li> <li>- analysis of defects in the provision of medical care, their legal qualifications.</li> </ul>	<p><b>The purpose of teaching the discipline.</b> One of the main objectives of this program is to improve the legal framework of the industry in accordance with international standards; implementation of legal, economic, administrative mechanisms, ensuring the constitutional rights of citizens to health care; therefore, medical law is an important discipline for any physician who, when necessary, should correctly apply the knowledge gained in practice.</p>

#### 4. Competencies and learning outcomes

As a result of studying the discipline students must

- **know** the conceptual and categorical apparatus in the field of medical law; sources of medical law; trends in rule-making and state policy in the field of health care; mechanisms for exercising the rights and obligations of the subjects of medical relations; legal conditions for conducting certain types of medical practice and their legal regulation; state and legal guarantees and mechanisms for the protection of human rights in the field of health care; defects in the provision of medical care, their legal qualifications; types of legal liability for health offenses; legal practice in the field of medical law, including 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 of exercising the rights and responsibilities of the subjects of medical relations; prepare the necessary legal documents; analyze the legal nature of certain 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 examinations and mechanisms for quality control of medical care; correctly assess the consequences of the professional activities of medical and pharmaceutical workers.

In accordance with the requirements of the Standard of higher education discipline provides for students' acquisition of **competencies**:

*Integrated*: ability to solve common and complex specialized tasks and practical problems in the process of learning that involves the research and/or implementation of innovation and is characterized by complexity and uncertainty of conditions and requirements

*General*:

- knowledge and understanding of the discipline "Medical law of Ukraine";
- ability to apply knowledge of medical law of Ukraine in practical situations;
- ability to select a strategy of communication;
- ability to work in a team;
- interpersonal skills;
- ability to communicate in the state language, both orally and in writing;
- ability to communicate in another language;
- skills in using information and communication technologies;
- ability for abstract thinking, analysis and synthesis, capacity to learn and to be trained modern;
- ability to evaluate and ensure the quality of work performed;
- certainty and persistence regarding tasks and responsibilities taken.

*Special (professional)*:

- to know the conceptual-categorical apparatus in the field of medical law; the sources of medical law;
- to know the types of legal liability for offences in the sphere of health care; legal practice in the areas of health law, including the European court of human rights;
- ability to assimilate legal conditions for the execution of certain types of medical practices and their legal regulation;
- ability to assess trends in rule-making and public policy in the field of health;
- ability to analyze defects of rendering of medical aid, their legal qualification.

#### Matrix of competencies

№	Competence	Knowledge	Skills	Communication	Autonomy and responsibility
1	2	3	4	5	6
<b>General competence</b>					
Ability to apply knowledge of forensic medicine and medical law of Ukraine in practical situations					
<b>Special competencies</b>					

1.	Ability to reasonably assess the results of defects in the provision of medical care, their legal qualifications.	Basic laws governing the activities of health professionals. Basic laws governing the activities of health professionals.	It is reasonable to evaluate the results of defects in the provision of medical care, their legal qualifications.	To explain goals and methods assessment of the results of defects in the provision of medical care, their legal qualifications in foreign and Ukrainian languages.	To be responsible for deciding on legal liability for health care.
2.	Ability to assess the legal conditions of certain types of medical practice and their legal regulation.	Duties, rights and responsibilities of medical workers for professional misconduct, as well as the basic laws governing the activities of medical workers.	To be able to analyze legal conditions for conducting certain types of medical practice and their legal regulation.	To explain the results of conduction certain types of medical practice and their legal regulation.	To be responsible for deciding on legal liability for health care.

### 5. Organization of course training

#### *The volume of the course*

Type of lesson	<b>Total amount of hours 45</b>
Lectures	6
Practical classes	14
Independent work	25

#### *Course signs*

Semesters: the 5th	Specialty 221"Dentistry"	Course (year of study) : the 3rd	Normative discipline
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#### *Course thematics*

The program of the discipline is structured into Module 1: Medical law of Ukraine.

#### **SPECIFIC GOALS:**

- to know the necessary conceptual minimum, without which it is impossible to form a general idea of the legal regulation of medical activity and responsibility for violations of legislation in this field;
- to know the legal acts that regulate the activities of healthcare professionals and legal relationships in the healthcare sector and be able to analyze them;
- to learn the causes of adverse effects in medical practice, medical errors, accidents;
- to be able to characterize and evaluate the offenses of healthcare professionals.

### THEMES OF LECTURES

#### The 5<sup>th</sup> semester

N <sup>o</sup>	Topics	Hours
1.	Medical law and its place in the system of Ukrainian law and legislation of Ukraine.	2
2.	Legal nature of medical care and medical services.	2
3.	Legal liability in the field of healthcare.	2
	TOTAL	6

## THEMES OF PRACTICAL LESSONS

### The 5<sup>th</sup> semester

№	Topics	Hours
1.	Medical law of Ukraine in the systems of law and legislation. International and regional standards in the field of health and human rights.	3
2.	Legal nature of medical care and medical services. The human rights system in the healthcare sector.	3
3.	Legal status of subjects of medical legal relations. Medical examination for the legislation of Ukraine.	3
4.	Legal liability in the field of healthcare. Procedures and mechanisms for the protection of the rights of subjects of medical relationships.	3
5.	<i>The final control (diff.credit)</i>	2
	<b>TOTAL</b>	<b>14</b>

## THEMES OF INDEPENDENT WORK OF STUDENTS

### The 5<sup>th</sup> semester

№	Topic	Hours
I.	Preparation for practical training - theoretical preparation and practical skills development	<b>8</b>
II.	Independent study of topics that are not included in the classroom plan:	<b>13</b>
1	Defects of care. Medical examination and quality control of medical care under the laws of Ukraine.	3
2	Legal regulation of family medicine in Ukraine. Traditional medicine (healing) under the laws of Ukraine.	2
3	Legislative support for prevention and treatment of infectious diseases. Legal support of sanitary and epidemiological welfare in Ukraine.	2
4	Legal support of reproductive health and reproductive technologies in Ukraine. Correction of sex.	2
5	Legal regulation of pharmaceutical proceedings and providing population with medical drugs and medical products in Ukraine.	2
6	International standards and national regulating authorities intellectual health. Legal regulation of care to vulnerable populations.	2
III.	Preparation for the final control of the assimilation of discipline "Medical law of Ukraine"	<b>4</b>
	Total	<b>25</b>

### 6. Course evaluation system

General course evaluation system	<p><b>Current control</b> is performed based on the control of theoretical knowledge, skills and abilities in practical classes. Independent study students are assessed in practical classes, and is an integral part of the final grade of the student. Current control is performed during the training sessions and aims at checking the assimilation of students learning the material. Forms of current control are:</p> <p>a) test tasks with a choice of one correct answer, with the definition of the correct sequence of actions, with</p>
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determination of the conformity, defining the specific portion of the photo or diagram ("detection");  
 b) individual oral questioning, interview;  
 c) the solution of typical situational tasks;  
 g) identification of pathogens and carriers of pathogens of parasitic diseases in the photographs, macro - and micropreparats;  
 d) control of practical skills;  
 e) the typical problems of genetics and medical genetics.

Grades on the national scale ("excellent" - 5, "good" - 4, "satisfactory" - 3, "unsatisfactory" - 2), received by students, are displayed in the journals of attendance and academic group performance.

**Final control**

The final control is the form of a differentiated credit at the end of the 1st semester and an exam at the end of the 2nd semester upon completion of the course of medical biology.

The semester exam is a form of final control of mastering by the student of theoretical and practical material on academic discipline. The final control (exam) is carried out at the last control lesson.

Students are admitted to the FC who have attended all the classes provided by the curriculum in the discipline and while studying the module scored the number of points not less than the minimum (72 points). A student who, for good or bad reasons, has missed classes, is allowed to rework academic debt for a certain period of time.

**Evaluation of current educational activities.** During the assessment of mastering each topic for the current educational activity of the student scores are set on a 4-point (national) assessment scale. This takes into account all types of work provided by the discipline program. The student must receive a score on each topic. Scores on the traditional scale are converted into points. The final assessment of the current academic activity is the arithmetic mean (the sum of scores for each lesson is divided by the number of lessons per semester) and translated into points according to Table 2.

**Table 2. Conversion of the average score for the current activity into a multi-point scale (for disciplines completed by diff.credit, exam)**

4-point scale	120-point scale	4-point scale	120-point scale	4-point scale	120-point scale	4-point scale	120-point scale
5	120	4,45	107	3,91	94	3,37	81
4,95	119	4,41	106	3,87	93	3,33	80
4,91	118	4,37	105	3,83	92	3,29	79
4,87	117	4,33	104	3,79	91	3,25	78
4,83	116	4,29	103	3,74	90	3,2	77

4,79	115	4,25	102	3,7	89	3,16	76
4,75	114	4,2	101	3,66	88	3,12	75
4,7	113	4,16	100	3,62	87	3,08	74
4,66	112	4,12	99	3,58	86	3,04	73
4,62	111	4,08	98	3,54	85	3	72
4,58	110	4,04	97	3,49	84	<3	Not enough
4,54	109	3,99	96	3,45	83		
4,5	108	3,95	95	3,41	82		

*The maximum number of points that a student can collect for current educational activity during semester in order to be admitted to the exam is 120 points.*

*The minimum number of points that a student can collect for current educational activity during semester in order to be admitted to the exam is 72 points.*

Calculating of the number of points is based on obtained marks of student according to traditional scale while learning subject during the semester, by calculating the arithmetic mean (AM) that is rounded to two signs after comma.

**Evaluation of independent work of students.** Independent work of students, which is provided by the topic of the lesson together with the classroom work, is evaluated during the current control of the topic in the relevant lesson. Assimilation of topics that are submitted only for independent work is checked during the final module control.

**Evaluation of final control.**

The maximum number of points that a student can score during the exam is 80 points.

The final control is considered credited if the student scored at least 60% of the maximum amount of points (for a 200-point scale - at least 50 points).

**Determining the number of points that a student scored in the discipline:** the number of points that a student scored in the discipline is defined as the sum of points for the current academic activity (Table 1) and for the final control (diff.credit, exam) (Table 3).

**Table 3. Scale of assessment of differentiated (exam) credit:**

Traditional scale	Points
«5»	70-80
«4»	60-69
«3»	50-59

Requirements for written work

The final written work is performed in the form of a test.

Practical classes

Classroom work

### The 3rd course. The Vth semester

**Module 1. Medical Law of Ukraine**

Topics 1-4:

Classroom work - score from 2 to 5 for each topic.

Topic 5: Diff.credit (Semester control): practical training, theoretical training.

Final module control1 is evaluated from 50 to 80 points and consists of:  
3 theoretical questions and 1 situational task.

**THE CRITERIA FOR EVALUATION  
PRACTICAL SKILLS AND THEORETICAL QUESTIONS**

Number of Situational task	«5»	«4»	«3»	The answer a card to the practical skills	For each answer to the practical skill student receives from 10 to 16 points: «5» - 16 points; «4» - 13 points; «3» - 10 points.
1	16	13	10		
Number of Theoretical question	«5»	«4»	«3»	Oral answer the card on theoretical questions	For each answer to the practical skill student receives from 10 to 16 points: «5» - 16 points; «4» - 13 points; «3» - 10 points.
1	16	13	10		
2	16	13	10		
3	16	13	10		
<b>The sum of points</b>	<b>80</b>	<b>65</b>	<b>50</b>		

Students who have completed all types of work provided by the curriculum and scored the number of points for the current success not less than the minimum (72) are admitted to the exam. The total grade for the module and the discipline consists of a total grade for the activities in the current classes and the final control of student knowledge. Current activity is estimated from 72 to 120 points. Thus, the minimum number of points per module should be:  $72 + 50 = 122$  points. Maximum number:  $120 + 80 = 200$  points.

**Rating scale:**

National scale	Points scale
«5»	70-80
«4»	60-69
«3»	50-59

**LIST OF THE QUESTIONS FOR DIFF. CREDIT**

1. Legal nature of medical law (branch of law, institute of law, branch of law).
2. Medical law of Ukraine as a legal entity: concept, tasks, subject of regulation.
3. Medical relationships: concepts, 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 a discipline and branch of science.
8. General Characteristics of Health Care Legislation in Ukraine.
9. acts in the field of health and human rights, containing mandatory rules and principles ("hard law") (in particular, the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social and Cultural Rights, The Convention on the Rights of the Child, the Convention on the Rights of Persons with Disabilities).
10. Regional acts in the field of health and human rights, which contain binding rules and principles ("hard law") (in particular, European Convention for the Protection of Human Rights and Fundamental Freedoms, European Social Charter, European Convention on the Protection of Human Rights and Fundamental Freedoms) human rights and biomedicine).

11. International health and human rights instruments containing guidelines and guidelines ("soft law") (in particular, the International Standard Rules for the Treatment of Prisoners, Principles for the Protection of Mentally Ill Persons and the Improvement of Mental Care, The Alma-Ata Declaration, the Lisbon Declaration of Patient Rights).
12. Regional health and human rights instruments containing guidelines and guidelines ("soft law") (in particular, the European Charter on Patients' Rights, the Declaration on Patient Rights in Europe, the Ljubljana Charter on healthcare reform).
13. The role and meaning of the Universal Declaration of Human Rights and its place in the system of international standards in the field of health and human rights.
14. Patients' rights under international health and human rights instruments.
15. The rights of health professionals under international instruments in the field of health and human rights.
16. Patients' rights under regional health and human rights instruments.
17. The rights of health care workers under regional health and human rights instruments.
18. Place and significance of European Union acts in the system of regional standards in the field of health and human rights.
19. The EU-Ukraine Association Agreement on Health.
20. Constitutional regulation of health care in Ukraine.
21. The role and significance of decisions of the European Court of Human Rights in the field of health, in the system of the legislation on health care of Ukraine, as well as documents of national courts.
22. The place of medical law in the system of social regulation of medical activity.
23. Systematization of the Ukrainian legislation on health care.
24. Health care institution of Ukraine.
25. General provisions on health insurance: concepts, principles of insurance, subjects, objects and content of the legal relationship.
26. Voluntary health insurance: state of the law and practice of application.
27. Formation and development of compulsory state social health insurance.
28. Professional liability insurance of medical workers.
29. Insurance of medical and pharmaceutical workers performing their professional duties in certain fields of medical activity.
30. Concepts and features of medical care (quality, qualified, affordable, free of charge).
31. The right to medical care under the legislation of Ukraine.
32. Medical service as an object of medical legal relations.
33. Medical Services Contract: Concepts, General Characteristics and Performance Features.
34. The concept and legal nature of the health care contract.
35. Human rights in health: concept, classification, general characteristics.
36. Guarantees of human rights in the field of health care.
37. Human right to life: concept, content and general characteristics. Right to life and medical practice: the issue of correlation.
38. The concept and structure of the human right to health care under the legislation of Ukraine.
39. Human right to health information: general characteristics and legal support.
40. Human right to medical secrecy: general characteristics and legal support.
41. The human right to consent to medical intervention.
42. The right to refuse medical intervention.
43. Concepts and types of subjects of medical legal relations.
44. Patient: definitional and classification approaches.
45. General characteristics of the patient's rights.
46. Legal regulation of the patient's responsibilities in Ukraine.
47. Features of legal status of legal representatives in the field of health care.
48. Legislative support and classification of the rights of medical professionals.
49. Legal regulation of the professional duties of health care professionals.
50. Legal status of a doctor under national law.

51. Concepts and types of procedures and mechanisms of protection of rights of subjects of medical legal relations.
52. Forms of protection of rights of subjects of medical legal relations: concepts, types, means of implementation.
53. Judicial form of protection of rights of subjects of medical legal relations in the order of constitutional and administrative judiciary.
54. Judicial form of protection of the rights of the subjects of medical legal relations in the procedure of civil proceedings.
55. Judicial form of protection of the rights of the subjects of medical legal relations in the procedure of criminal proceedings.
56. Extra-judicial form of protection of rights of subjects of medical legal relations: concepts, types, general characteristics.
57. Health Offenses as a Ground for Legal Liability in Medical Law: Concepts, Signs, Composition.
58. Concepts and types of legal liability of subjects of medical legal relations.
59. Civil liability in the field of health care.
60. Disciplinary responsibility of medical professionals.
61. Administrative liability in medical law.
62. Criminal liability of medical professionals in connection with their professional activity.
63. Exemption from legal liability of medical professionals.
64. Non-jurisdictional forms of protection of the rights of subjects of medical legal relations: concepts, types, general characteristics.
65. International forms and remedies for the subjects of medical legal relationships.
66. Legal practice in the field of medical law.
67. Features of legal liability of patients under the legislation of Ukraine.
68. Expertise in the field of health care: national and foreign legislation.
69. The concept, types and meaning of medical expertise in Ukraine.
70. Expert opinion: form and content.
71. Medical and social expertise of disability: concepts and types.
72. Forensic examination: general characteristics and role in the field of medical law.
73. Forensic psychiatric examination: general characteristics and role in the field of medical law.
74. Forensic psychological examination: general analysis and role in the field of medical law.
75. Medical examination: general characteristics and role in the field of medical law.
76. Alternative medical expertise: general analysis and role in medical law.
77. Pathological section: features of conduct, role and importance for medical affairs.
78. Defects in medical care: concepts and types.
79. Medical error and accident.
80. Quality control of medical care: concepts, types, subjects.
81. General characteristics of primary care.
82. General characteristics of secondary care.
83. General characteristics of tertiary care.
84. General characteristics of emergency medical care.
85. General characteristics of palliative care.
86. General characteristics of medical rehabilitation.
87. Legal status of primary care physician.
88. International and regional standards and national acts on intellectual property in the field of health care.

**Circumstance of admission to the final control**

1. Semester control at the end of the 1st semester is provided in the form of a differential credit. (Table 2) Provides a final score on a 120-point scale as the sum of scores for the current control of knowledge (oral\* examination, written survey, tests,

	<p>verification of identification of micropreparations, abstracts), the results of 2 content modules.</p> <p>2. Students are allowed to take the differentiated credit, exam only if there is no debt for the implementation of the curriculum.</p>
<b>7. Course policy</b>	
<p>The organization of the educational process is carried out with the use of the European Credit Transfer System (ECTS) to assess student performance. The points gained in the current survey, independent work and points of the final control are credited. This must take into account the student's presence in class and his activity during practical work. Inadmissible: absences and late classes; use of a mobile phone, tablet or other mobile devices during the lesson (except for the cases provided by the curriculum and methodical recommendations of the teacher); copying and plagiarism; untimely performance of the task, the presence of unsatisfactory grades for 50% or more of the submitted theoretical and practical material.</p>	
<b>8. RECOMMENDED LITERATURE</b>	
<p><b>Basic:</b></p> <ol style="list-style-type: none"> <li>1. Medical law Ukraine: practicum / I.Y. Senyuta, I.A. Bohomazov, A. Kashyntseva, D.Y. Coarse, R.A. Maidanyk, E.E. Sichkoriz, H. Ya.</li> <li>2. Health care and human rights. Resource guide / John. Koen, T. Ezer, P. McAdams, M. Milof; trans. from English by N. Shevchuk; ed. Of Ukrainian version I. Senyuta - 5th ed. Lviv: LOBF "Medicine and Law", 2011. 600 p.</li> <li>3. Senyuta I. International legal standards in health care // Bulletin of the Lviv National University. Series legal. Vol. 40. Lviv, 2004. P. 24-36.</li> <li>4. Modern Ukrainian medical law: monograph / ed. S.G. Stetsenko. K.: Atika, 2010. 496 p.</li> </ol>	<p><b>Additional:</b></p> <ol style="list-style-type: none"> <li>1. Gladun Z.S. Ukraine's legislation on health care: concept, content, problems and prospects of Ukraine // Legislation on Health Care: a collection of standard acts. - K.: YurinkomInter, 2000. P. 10.</li> <li>2. Gutorova N., Zhytnyi O., Kahanovska T. Medical negligence subject to criminal law. <i>Wiadomosci lekarskie</i>. № 11 cz 1. 2019.</li> <li>3. Medico-Legal explanatory dictionary / compilation by I. Y. Senyuta, I.J. Tereshko, N.E. Farmers, O. Tsybak; ed. I. Y. Senyuta. Lviv: LOBF "Medicine and Law", 2010.</li> <li>4. Medical Legislation: legal regulation of medical practice. Bk. 2: textbook / T.S. Gruzieva, N.V. Banchuk, V.F. Moskalenko, B.V. Mikhaylichenko, I. Khmil, A.I. Artemenko. Kyiv: VSV "Medicine", 2011.</li> <li>5. Ukraine Medical law: the textbook / under total ed. Doctor of Law, Professor. S.G. Stetsenko. Kyiv: All-Ukrainian Association of Publishers "legal unity", 2008. 507 p.</li> </ol>

Lector Реч Ph.D. K. Varukcha.