

MINISTRY OF HEALTH OF UKRAINE  
ZAPOROZHYE STATE MEDICAL UNIVERSITY  
DEPARTMENT OF MANAGEMENT AND ECONOMICS  
PHARMACEUTICAL, MEDICAL AND PHARMACEUTICAL LAW

## *Medical law*



Workshop for practical lessons and independent work of students of the  
Faculty of International  
speciality "Medicine"

Zaporozhye - 2016

## Workshop for practical lessons and independent work of students of the Faculty of International, speciality "Medicine"

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Practical class is a form of studying, which aims to enhance the knowledge received by students during lectures, forming their skills and experience in the application of knowledge, skills of creative thinking, analysis and resolving of various legal situations.

Practical exercises enable to expand and systematize the knowledge of the discipline. During preparation for the practical classes student shall: 1) learn to analyze recommended sources, relating to the topic of a practical class, know how to outline necessary material; 2) summarize the knowledge received from various sources; 3) prepare answers to theoretical questions and perform all the tasks that are provided within the theme of practical class.

Topics of practical class are disposed in successive order and elucidate the topics of practical classes, provided by the Working educational program for students of medical faculty who are studying for specialties 7.12010001 «Medicine» on the discipline «Medical law».

Every topic of practical class contains the list of theoretical (problematic) questions which relate to topics of practical class, questions for self-control and creative tasks.

A student shall prepare the answers to theoretical questions himself on the basis of the recommended resources, which relate to the practical class. Preparation of written answers to theoretical questions is optional, but during the practical class when providing an answer to one of the theoretical questions a student shall provide a clear and reasoned response, which is supported by the relevant sources of law, recommended literature and legal practice.

Questions for self-control and creative tasks are performed by student in written. Answers to the self-control questions should be clear and reasoned. Creative tasks shall be prepared in written form and should include a clear answer to a question with reference to valid legislation. When solving tasks of the practical class students shall provide clear answers and need to be ready to answer additional questions that may be given by a lecturer or other students.

## Thematic class of practical classes

Theme	Number of hours
<b>Content module 1. Medical Law as a Legal Phenomenon</b>	<b>4</b>
Medical law in the system of law and system of legislation.	1
Legal regulation of the system of health care system in Ukraine	1
International standards in the sphere of health care and human rights. Regional standards in the sphere 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>6</b>
Legal status of medico-legal relations subjects	2
The system of human rights in patient care. Personal non-property rights.	2
Defects of medical care. Medical examination and control over the quality of medical care under the legislation of Ukraine	1
Legal liability in the sphere of health care. Procedures and mechanism for the rights protection of medico-legal relations subjects	1
<b>Total</b>	<b>10</b>

# **Content module 1.**

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

### ***Brief information materials for practical training on the topic of the module 1***

Medical law is a set of regulations that determine the organizational, structural, common law relationship in the provision of preventive and curative care for people carrying out sanitary and anti-epidemic measures and other actions related to health activities.

The subject of medical law is a legal relationship in the implementation of preventive and curative, sanitation activities and regulations that define the legal status of the participants of these relations.

Three subject of medical law: medical organization (institution), healthcare professionals and patients.

Medical organization is subject to the provision of medical care.

The subject is a medical aid worker who has professional knowledge.

The patient is subject to receive medical treatment.

The Principles of Medical law. These include principles: social justice, humanism, equality, the rule of law and the unity of legal rights and obligations.

Legal regulation of the health care system is carried out in the Constitution.

The Fundamentals of the Ukrainian legislation on health care, the Laws of Ukraine:

"On ensuring sanitary and epidemiological welfare of the population"

"On protection of the population against infectious diseases"

"On Prevention of Acquired Immune Deficiency Syndrome (AIDS) and Social Protection of the Population"

"On the fight against tuberculosis"

"On psychiatric care"

"On Medicines"

A fundamental of the Ukrainian legislation on health care is determined: legal, organizational, economic and social basis of health protection in Ukraine.

Regulates public relations in order to ensure the development of physical and spiritual strength, high disability and long active life of citizens, eliminating the factors which could adversely affect their health, prevent and reduce disease, disability and mortality, improving heredity.

The legislation of Ukraine contains its definition of health: Health - a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

Health care - a system of measures aimed at ensuring the preservation and development of physiological and psychological functions, the optimal capacity for work and social activity of the person at the maximum biologically possible individual life expectancy.

Medical assistance - work professionally trained health workers, aimed at prevention, diagnosis, treatment and rehabilitation in

connection with diseases, injuries, poisonings and pathological conditions, as well as in connection with pregnancy and childbirth.

Emergency state of a person - a sudden deterioration in physical or mental health, which is a direct and imminent threat to the life and health of the person or the people around her and arises as a result of illness, injury, poisoning or other internal or external causes.

***Theme. Medical law in the system of law and system of legislation. Legal regulation of the health care system in Ukraine***

**Plan of the practical class**

1. Medical law as a branch of law: notion, subject, methods, system and sources.
2. Legal relations in health care: concept, types, and composition.
3. Medical law as an academic discipline and a field of science.
4. Participants and objects of legal relations in health care sphere.
5. Sources of law that govern the relations in health care sphere.
6. Commercial activity in the sphere of health care. Procedure and conditions for licensing of medical practice.
7. Health care facility as a subject of commercial activity in the sphere of health care. Accreditation and licensing of health care facilities.
8. Voluntary and compulsory medical insurance.
9. Legal nature of medical care and medical service. Medical services contract.



## **Self-control questions**

1. Define the term «medical law».
2. Describe medical law as part of the legal and medical sciences.
3. Describe medical law as an academic discipline.
4. Suggest the definition of "medical law as a branch of law".
5. Identify basic features that characterize medical law as a branch of law.
6. Give the definition of "subjects of medico-legal relations" and name its types.
7. What is the classification of sources of law governing the relations in health care?
8. Provide the definition of a health care facility.
9. Provide the definition of the terms “medical service” and “medical care”.
10. What are the peculiarities of compulsory and voluntary medical insurance?

### ***Theme. International and regional standards in the sphere of health care and human rights***

#### **Plan of the practical class**

1. The international level of standards: the concept, character and system.
2. General and theoretical description of international legal standards.
3. International acts in the field of health care and human rights which contain binding rules and principles:

- International Covenant on Civil and Political Rights;
  - International Covenant on Economic, Social, and Cultural Rights;
- 
- Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine;
    - Convention for the Protection of Human Rights and Fundamental Freedoms;
    - European Social Charter.
4. International acts in the field of health care and human rights, which contain recommendation standards and principles:
- Declaration of Alma-Ata;
  - The Maastricht Guidelines on Violations of Economic, Social, and Cultural Rights;
  - European Charter of Patients' Rights.
5. Patients' rights under the international standards of human rights in patient care.
6. Health professionals' rights under the international standards of human rights in patient care.
7. The regional level of standards: the concept, character and system.
8. Regional standards in health care established by the Council of Europe (European Convention on Human Rights, the European Social Charter, the European Convention on Human Rights and Biomedicine, etc.).
9. The place and importance of European Union's legislation in the system of regional standards in health care and human rights.

## Self-control questions

1. What is the role of international standards in the regulation of health care?
2. Give the definition of "international standards of human rights in patient care".
3. Characterize the system of international standards in the field of health care.
4. What human rights in patient care as they are fixed in the international standards do you know? Which ones are the most significant in your opinion and why?
5. Name several (at least 4) legal acts that establish international standards of patient's rights.
6. Characterize the role of the European Court of Human Rights judgments in the system of regional standards in the sphere of human rights in patient care.
7. How important is the activity of Council of Europe in formation of regional level of standards in the field of health care?
8. What is the difference between regional standards in the field of health care that are made by different international regional organizations?
9. What are the peculiarities of regional standards that exist in European Union?
10. What institutions of the European Union participate in the creation of regional standards and ensure their functioning?

## **Content module 2.**

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

#### ***Brief information materials for practical training on the topic of the module 2***

All patients in Ukraine (including foreigners staying in Ukraine on legal grounds) in accordance with the Lisbon Declaration of the World Medical Association on the rights of patients and the development of the Declaration on the rights of patients in Europe have the following rights in health care (The Law of Ukraine "Fundamentals of the Ukrainian legislation on health care"):

- the right to dignity and self-respect;
- the right to self-determination;
- right to preserve the physical and mental integrity and inviolability;
- the right to freedom of choice;
- the right to information;
- the right to informed consent;
- the right to seek the opinion of another physician at any stage of treatment;
- right to privacy;
- the right to quality health care;
- the right to medical and social education;
- the right to religious assistance and support.

Patient Responsibilities:

- take care of your health and the health of children, not to harm the health of others;
- pass preventive medical inspections and vaccinations;
- to provide emergency assistance to other citizens, threatened their lives and health status;

#### Professional duties medical workers.

Medical workers must:

- a) promote the protection and strengthening of health, prevention and treatment of diseases, to provide timely and quality medical assistance;
- b) provide appropriate free emergency medical assistance to citizens in case of accidents and other emergency situations;
- c) disseminate scientific and medical knowledge among the population, to promote, including by example, healthy lifestyle;
- d) comply with the requirements of professional ethics and deontology, maintain medical confidentiality;
- d) continuously raise the level of professional knowledge and skills;
- e) provide advice to their colleagues and other health professionals.

The patient - a natural person, seek medical help and / or provide such assistance.

Medical assistance is divided into types of emergency, primary, secondary (specialized), tertiary (highly specialized), palliative care, medical rehabilitation.

The attending physician - health facilities doctor or carrying out business activity in medical practice as a natural person - entrepreneur and providing medical aid to a patient during his examination and treatment.

Emergency medical assistance - medical assistance, which consists in the implementation of health care professionals in accordance with the law of the urgent organizational, diagnostic and therapeutic measures aimed at saving and preserving human life in an urgent condition and minimize the consequences of such a state of health.

Primary medical care - medical care provided in outpatient settings or residence (stay) the patient's general practitioner - family physician and provides consultation, diagnosis and treatment of common diseases, injuries, poisonings, pathological, physiological (pregnancy ) states, implementation of preventive measures; direction according to the medical condition of the patient that needs emergency medical care, to give it a secondary (specialized) or tertiary (highly specialized) medical care; emergency aid in the event of an acute disorder of physical or mental health patient who requires urgent, secondary (specialized) or tertiary (highly specialized) medical care.

The secondary (specialized) medical care - medical care provided in outpatient or inpatient physicians relevant specialization (except general practitioners - family doctors) routinely or in an emergency, and provides advice, diagnosis, treatment, rehabilitation and prevention , injuries, poisonings, pathological and physiological (pregnancy and birth) states; sending the patient under medical indications for the provision of secondary (specialized) medical assistance from another specialization or tertiary (highly specialized) medical care.

Tertiary (highly specialized) medical care - medical care provided in outpatient or inpatient routinely or in an emergency, and provides consultation, diagnosis and treatment of diseases, injuries, poisonings,

pathological conditions, maintaining physiological conditions (pregnancy and childbirth) using high-tech equipment and / or highly specialized medical procedures of high complexity; sending the patient under medical indications for the provision of secondary (specialized) care or tertiary (highly specialized) medical assistance from another specialization.

In the course of the last stages of incurable diseases patients given palliative care, which includes measures aimed at alleviating physical and emotional suffering of patients and providing psychosocial and moral support to their families.

Palliative care is provided free of charge by sending health institution where the patient is given a secondary (specialized) or tertiary (highly specialized) medical care, which concluded an agreement on health services.

Medical rehabilitation - the kind of care provided to patients in an outpatient or inpatient and includes a system of health and other measures to restore the violated or lost functions of the person in the identification and activation of compensatory capacity of the organism to create conditions for the return of a person to normal life on the prevention of complications and relapses.

#### Medical secrecy.

Health care workers and others who are in connection with professional or duties became aware of the disease, medical examination, examination results and their intimate and family life of citizens, not disclose this information, except as provided by legislative acts cases.

When using the information of medical confidentiality, the learning process, research work, including in cases of its publication in the literature should be ensured the anonymity of the patient.

### **Theme. *Legal Status of Medico-Legal Relations Subjects***

#### **Plan of the practical class**

1. Legal regulation of patient rights: international standards and national laws.
2. Patients' rights in specific spheres of medical practice.
3. Legal regulation of patient responsibilities in Ukraine.
4. Legal regulation of professional rights and responsibilities of medical workers.
5. Legal status of physician in charge under the laws.
6. Legal status of the health care institution under the laws.
7. Legal status of patient's legal representative.
8. Professional ethics and medical deontology in medical practice.

#### **Self-control questions**

1. What conditions are necessary for acquiring the status of patient?
2. Analyze the essence of patient rights who is an inpatient in a health care facility, for access to him other medical professionals.
3. What are the general responsibilities of the patient, according to current legislation of Ukraine and your country?
4. Analyze the content of the patient's obligation to perform doctor's medical prescriptions and legal consequences for their non-fulfillment.



5. What are the specific responsibilities of the patient, according to current legislation of Ukraine and your country?
6. Give the definition of medical professional.
7. Name the rights of medical professionals in the course of medical care provision.
8. What requirements apply to a person who intends to engage in medical or pharmaceutical activity?
9. What legal restrictions are foreseen by the laws of your country as regards to medical and pharmaceutical workers in the course of their professional activities fulfillment?
10. Outline features of the legal status of a physician under the laws of Ukraine and your country.

***Theme. The system of human rights in patient care. Personal non-property rights.***

### **Plan of the practical class**

1. Human rights in patient care: notion, classification and general characteristics.
2. Human rights to life and medical practice: correlation problem.
3. Human right to health care.
4. Human rights to medical care. Right to consent and refusal from medical interference.
5. Human right to medical information: general characteristics and legal regulation.

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

7. Human rights of a person who is on in-patient treatment.

### **Self-control questions**

1. Give the definition of the term “medical information”.

2. Explain the correlation between medical information and medical secret.

3. What is e-health?

4. Give the definition of euthanasia and enumerate its types.

5. Give the definition of medical care and highlight its main features.

6. What is the difference between medical secret and physician’s secret.

7. Provide 4-5 examples when disclosure of medical information is lawful.

8. Explain three main features of consent to medical interference: informed, voluntary, competent.

9. Who is entitled to sign the relevant consent for medical treatment documents for a minor patient?

10. What is patient autonomy?

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

***Theme. Legal liability in the sphere of health care. Procedures and mechanism for the rights protection of medico-legal relations subjects.***

## **Plan of the practical class**

1. Defects of medical care: concepts and types.
2. Legal assessment of defects of medical care.
3. Concept, types and importance of medical examinations in Ukraine.
4. Iatrogenic disease:
  - a) definition, classification of iatrogeny;
  - b) main causes of iatrogenic diseases;
  - c) place of iatrogeny in the structure of the adverse outcomes of medical interventions.
5. Medical error: the concept, characteristics, legal significance.
6. Health care quality monitoring. Bodies, responsible for monitoring of health care quality in your country.
7. Legal responsibility of medical legal relations subjects: definition, types:
  - a) civil liability in the sphere of health care;
  - b) disciplinary liability of medical workers;
  - c) administrative liability of medical workers;
  - d) criminal liability of medical workers for committing of professional crimes.
8. Release from legal responsibility of medical professionals.
9. Concept and types of forms of medico-legal relations subjects' rights protection.
  - a) judicial form of rights protection of medical legal relation subjects;
  - b) extra-judicial form of rights protection of medical legal relation subjects;

c) non-jurisdictional form of rights protection of medical legal relation subjects.

### **Self-control questions**

1. What forms of medical legal relation subjects' rights protection do you know?
2. What types of legal liability for violations of health care are foreseen by the current laws of Ukraine and your country?
3. Research the essence of civil responsibility in the sphere of health care.
4. Outline the procedure of engaging to discipline responsibility of medical worker based on the conclusion of clinical expertise of the identified deficiencies?
5. What is the difference between the disciplinary and criminal responsibility of medical professionals?
6. What types of medical mistakes do you know?
7. Enumerate the cases when a forensic medical examination is conducted.
8. What is the difference of internal and external control over medical care quality?
9. Define the essence of iatrogenic disease.
10. Who is responsible for carrying out a forensic medical (pshychological, pshychiatric) examination in your country?

## Self-reliant work of students and its control

Theme	SRW	Type of control
<b>Content module 1. Medical Law as a Legal Phenomenon</b>	<b>6</b>	
Medical law in the system of law and system of legislation	<b>1</b>	<b>Current control during practical classes</b>
Legal regulation of the system of health care system in Ukraine	<b>1</b>	
International standards in the sphere of health care and human rights	<b>2</b>	
Regional standards in the sphere of health care and human rights	<b>2</b>	
<b>Content module 2. Legal Status of Medico-Legal Relations Subjects and Mechanisms of their Rights Protection</b>	<b>6</b>	
Legal status of medico-legal relations subjects	<b>1</b>	<b>Current control during practical classes</b>
The system of human rights in patient care. Personal non-property rights	<b>1</b>	
Defects of medical care. Medical examination and control over the quality of medical care under the legislation of Ukraine	<b>2</b>	
Legal liability in the sphere of health care. Procedures and mechanism for the rights protection of medico-legal relations subjects	<b>2</b>	
<b>Content module 3. Legal Regulation of Certain Types of Medical Activity</b>	<b>13</b>	
Legal regulation of family medicine in Ukraine. Folk medicine (healing) under the laws of Ukraine	<b>1</b>	<b>Current control during practical</b>
Legal regulation of prophylactics and treatment of infectious diseases. Legal regulation of sanitary and	<b>2</b>	

epidemiological welfare in Ukraine		<b>classes</b>
Donation under the laws of Ukraine. Legal regulation of reproductive health and reproductive technologies in Ukraine. Gender adjustment	<b>2</b>	
Legal regulation of carrying out pharmaceutical activity and providing the population with medicines and medical equipment in Ukraine. Intellectual property in the sphere of health care	<b>2</b>	
Legal regulation of psychiatric care. Legal regulation of providing medical care to the vulnerable groups of the population	<b>2</b>	
Legal regulation of palliative care. Legal organization of hospices functioning in Ukraine	<b>2</b>	
Legal regulation of cosmetology and sports and fitness activity (sports medicine). Sanatorium and spa activity. Medical tourism.	<b>2</b>	
<b>Total</b>	<b>25</b>	

## **Content module 1.**

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

**Theme.** *Medical law in the system of law and system of legislation.*

**Objective:** clarify the legal essence of the notion “medical law”, its place and role in the system of law and legislation. Study the principles, functions and system of medical law.

#### **A student should know:**

- List of key legal acts on the topic;
- Notion of medical law;
- Sources of medical law;
- Principles and functions of medical law.
- System of legislation of Ukrainian legislation in the sphere of health care

#### **A student should be able to:**

- Analyze relevant law in the sphere of health care;
- Develop a necessary notion and categorical apparatus;
- Characterize a system of medical law;
- Define key functions and principles of medical law.

#### **Plan of the class**

1. Legal regulation of health care in Ukraine and a specific country.
2. Principles and functions of medical law.

3. System of medical law.
4. Sources of medical law
5. System of Ukrainian health care legislation.

### **Self- control questions**

1. What is medical law?
2. Describe the system of medical law.
3. What functions of medical law do you know?
4. Differentiate medical law from other branches of law.
5. What principles of medical law do you know?
6. Explain the definition of medical law as a branch of law.
7. Explain the definition of medical law as a field of science.
8. Explain the definition of medical law as an academic discipline.
9. What scientific approaches to defining the essence of medical law do you know?
10. Describe the system of sources of medical law.

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

**Objective:** Study the notion and categorical apparatus in the sphere of medical law, sources and types of medical law, trends of law-making in the sphere of health care. Analysis of the national laws in the sphere of health care.

**A student should know:**



- List of key legal acts on the topic;
- International and regional standards in the sphere of health care;
- Legal regulation of the system of health care in Ukraine;
- Procedure of the application of the court practice.

**A student should be able to:**

- Analyze current laws in the sphere of health care;
- Characterize international and regional standards in the sphere of health care;
- Outline necessary notion and categorical apparatus;
- Analyze relevant laws in the sphere of health care.

**Plan of the class**

1. History of legal regulation of the health care system in Ukraine.
2. General characteristics of the legislation in the sphere of health care in Ukraine. Classification of the legal acts.
3. Validity of the legal acts in time, space and scope of persons.
4. Constitution of Ukraine and laws of Ukraine as a source of medical law.
5. By-laws in the sphere of health care.
6. Local legal acts as a source of medical law of Ukraine.
7. Judgments of the Constitutional Court of Ukraine as a source of medical law.

## Self-control questions

1. Place the following legal acts in the ascending order taking into account their legal force.
  - Law of Ukraine “Principles of Ukrainian Health Care Legislation”;
  - Civil Code of Ukraine;
  - Order of the Ministry of Health of Ukraine;
  - Constitution of Ukraine;
  - Charter of the Health Care Facility;
  - International Covenant on Economic, Social and Cultural Rights.
2. What are the features of the local legal act as a source of medical law?
3. Describe a procedure of legal acts coming into force and recognizing stale.
4. What does the statement “Norms of the Constitution are norms of direct legal force” mean?
5. Is it a correct statement “In case of a collision between two Laws of Ukraine, there should be applied the one, which has a regulatory influence”?
6. In what way should be resolved a collision between general and special legal act?
7. Name at least 3 Laws of your country, which are related to the human rights in patient care.
8. Name at least 3 by-laws of your country, which are related to the human rights in patient care.

9. Which of the following legal acts has superior legal force? Constitution of Ukraine and International Covenant on Economic, Social and Cultural Rights.
10. Describe the system of legislation in the sphere of health care of your country.

**Theme. International standards in the sphere of health care and human rights.**

**Objective:** study the system of international standards of human rights in patient care, their types and features, learn relevant rights and responsibilities of patients and medical professionals under the regional standards.

**A student should know:**

- The system of international standards of human rights in patient care;
- International standards that contain binding rules;
- International standards that contain non-binding rules;
- Rights and responsibilities of patients and medical professionals under international standards.

**A student should be able to:**

- Analyze international standards of human rights in patient care;
- Differentiate the legal importance of binding and non-binding international standards of human rights in patient care;

- Apply relevant provisions of international standards of human rights in patient care;
- Characterize relevant enforcement mechanisms of international standards of human rights in patient care.

### **Plan of the class**

1. International framework of human rights in patient care;
2. General characteristics of binding international standards of human rights in patient care;
3. General characteristics of non-binding international standards of human rights in patient care;
4. Rights and responsibilities of patients and medical professionals under the international standards.
5. Key enforcement mechanisms of the international standards of human rights in patient care.

### **Self- control questions**

1. What elements make up the system of international standards of human rights in patient care?
2. Enumerate at least 5 international standards, which are binding for your country.
3. Enumerate at least 5 non-binding international standards of human rights in patient care.

4. What is the difference between international and regional standards of human rights in patient care?
5. What rights and responsibilities of patients under international standards do you know?
6. What rights and responsibilities of medical professionals under international standards do you know?
7. What enforcement mechanisms of international standards of human rights in patient care do you know?
8. What is the difference between the right to health and the rights to be healthy in the opinion of the International Committee on Economic, Social and Cultural Rights?
9. What do the terms availability and accessibility of health care mean?
10. Enumerate at least 5 examples of violations of human rights in patient care, foreseen by the international standards do you know?

**Theme. *Regional standards in the sphere of health care and human rights.***

**Objective:** study the system of regional standards of human rights in patient care, their types and features, learn relevant rights and responsibilities of patients and medical professionals under the regional standards.

**A student should know:**

- The system of regional standards of human rights in patient care;
- Regional standards that contain binding rules;

- Regional standards that contain non-binding rules;
- Rights and responsibilities of patients and medical professionals under regional standards.

**A student should be able to:**

- Analyze regional standards of human rights in patient care;
- Differentiate the legal importance of binding and non-binding regional standards of human rights in patient care;
- Apply relevant provisions of regional standards of human rights in patient care;
- Characterize relevant enforcement mechanisms of regional standards of human rights in patient care.

**Plan of the class**

1. Regional framework of human rights in patient care;
2. General characteristics of binding regional standards of human rights in patient care;
3. General characteristics of non-binding regional standards of human rights in patient care;
4. Rights and responsibilities of patients and medical professionals under the regional standards.
5. Key enforcement mechanisms of the regional standards of human rights in patient care.

## Self- control questions

1. What elements make up the system of regional standards of human rights in patient care?
2. Enumerate at least 5 regional standards, which are binding for your country.
3. Enumerate at least 5 non-binding regional standards of human rights in patient care.
4. What is the difference between international and regional standards of human rights in patient care?
5. What rights and responsibilities of patients under regional standards do you know?
6. What rights and responsibilities of medical professionals under regional standards do you know?
7. What enforcement mechanisms of regional standards of human rights in patient care do you know?
8. Enumerate at least 5 examples of violations of human rights in patient care, foreseen by the international standards do you know?
9. What patient's rights does the European Charter of Patient Rights foresee?
10. What does the right to respect of patient's time mean?

## **Content module 2.**

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

**Theme.** *Legal status of medico-legal relations subjects*

**Objective:** learning a legal status of a patient and medical professional, studying key professional rights and responsibilities of a physician in charge as well of other subjects of medico-legal relations.

#### **A student should know:**

- List of key legal acts on the topic;
- Basics of legal status of medico-legal relations subjects;
- Rights and responsibilities of patients and their legal representatives;
- Rights and responsibilities of medical professionals.

#### **A student should be able to:**

- Analyze current legislation in the sphere of health care;
- Characterize relevant notion-categorical apparatus;
- Prepare drafts of necessary legal documents;
- Respect rights and responsibilities of medico-legal relations subjects.

#### **Plan of the class**

1. Legal regulation of patient's rights: international and regional standards and national legislation.
2. Legal regulation of patient's responsibilities in Ukraine.



3. Legal regulation of professional rights and duties of medical professionals.
4. Legal status of a physician in charge.
5. Legal status of legal representatives and other medico-legal relations subjects.
6. Professional ethics and medical deontology in medical practice.

### **Self- control questions**

1. What patient rights do you know?
2. What rights of medical professionals do you know?
3. Enumerate three patient's responsibilities.
4. Enumerate 5 medical professional's responsibilities.
5. What is medical confidentiality?
6. Describe the right of the patient to medical information.
7. Describe the right of the patient to respect of his dignity.
8. Name at least 4 legal acts of your country, which regulate patient rights.
9. Name at least 5 legal acts of your country, which regulate rights and responsibilities of medical professionals?
10. Describe the rights of the patient, who stays on in-patient treatment?

**Theme. *The system of human rights in patient care. Personal non-property rights.***

**Objective:** form a basic knowledge as regards to the system of personal non-property rights in the sphere of health care, study the ways of realization of these rights.

**A student should know:**

- List of key legal acts on the topic;
- International and regional standards in the sphere of health care and human rights;
- List of key personal non-property human rights in the sphere of health care;
- Peculiarities of the personal non-property human rights in patient care realization

**A student should be able to:**

- Analyze relevant laws in the sphere of health care;
- Create conditions for the realization of personal non-property rights by the patients and their legal representatives;
- Prepare drafts of necessary legal documents;
- Apply relevant procedures for the personal data protection in the sphere of health care.

**Plan of the class**

1. Human rights in patient care: notion, types and characteristics.

2. Human right to life.
3. Human rights to health care.
4. Human rights to medical care. Right to consent and refuse from medical treatment.
5. Human rights to medical information: general characteristics and legal regulation.
6. Human right to medical confidentiality: general characteristics and legal regulation.
7. Procedure of personal data processing in the sphere of health care.

### **Self-control questions**

1. Give the definition of the term “human rights in patient care”;
2. Suggest a classification of the human rights in patient care;
3. What human rights in patient care should be considered basic?
4. Which groups of the population should be entitled to certain kinds of privileges in the sphere of health care?
5. Name at least 3 international legal acts, which are dedicated to human rights in patient care.
6. Describe human right to life.
7. Characterize legal regulation of human death. What is a brain death?
8. Suggest a definition of the term euthanasia and enumerate its types.
9. What are personal non-property human rights?
10. Describe human right to respect of dignity in terms of human rights in patient care.

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

**Objective:** studying the means of legal evaluation of defects of medical care, learning legal issues of medical care quality monitoring.

**A student should know:**

- Key legal acts on the topic;
- Key legal basics of medical care quality monitoring;
- Means of legal evaluation of medical care quality.

**A student should be able to**

- Analyze key legal acts on the topic;
- Describe a procedure of monitoring a quality of medical care;
- Provide legal qualification of defects of medical care.

**Plan of the class**

1. Notion, types and importance of medical examinations
2. Legal status of an expert under the legislation of Ukraine. Legal importance of the experts opinion.
3. Defects of medical care: notion and types.
4. Medical error as a medical-law phenomenon
5. Legal evaluation of defects of medical care.
6. Procedure of medical care quality monitoring.

## Self-control questions

1. Give a definition of the term medical error.
2. Explain the mediation procedure in the sphere of health care.
3. Describe key elements of medical violation.
4. What types of legal liability in the sphere of health care do you know?
5. Describe the essence of civil liability in the sphere of health care.
6. Name types of expenses, which are included into the amount of material compensation of material damages.
7. Describe the peculiarities of legal liability in the sphere of health care.
8. Name violations in the sphere of health care for which criminal responsibility is foreseen.
9. Describe peculiarities of clinic-expert commissions.
10. What is the difference between medical error and iatrogenic disease?

**Theme.** *Legal liability in the sphere of health care. Procedures and mechanisms for the rights protection of medico-legal relations subjects*

**Objective:** studying the issues of legal liability in the sphere of health care as well as algorithms and mechanisms of human rights protection in this sphere.

**A student should know:**

- List of key legal acts on the topic;
- Basics of legal liability in the sphere of health care;
- Mechanisms of human rights in patient care protection.

**A student should be able to:**

- Analyze current laws in the sphere of health care;
- Prepare drafts of necessary legal documents;
- Provide for the protection of human rights in patient care.

**Plan of the class**

1. The notion and forms of human rights in patient care protection.
2. Judicial form of human rights in patient care protection.
3. Non-judicial form of human rights in patient care protection.
4. Non-jurisdictional forms of human rights in patient care protection; self-defense, alternative conflicts resolution, applying to professional medical associations etc.
5. International forms and means of human rights in patient care protection.
6. The notion and types of legal liability in the sphere of health care. Grounds for release from criminal responsibility.
7. Compensation of moral damages for non-providing or improper medical care provision: theoretical and practical means of protection.

## **Self-control questions**

1. Provide a definition of the term “medical mistake”.
2. Describe a procedure of mediation in the sphere of health care.
3. What elements of a medical offence do you know?
4. What types of legal liability for the human rights in patient care violations do you know?
5. Describe civil liability for medical offence.
6. Describe criminal liability for medical offence?
7. Describe disciplinary liability of medical professionals?
8. Describe a procedure of monitoring a medical care quality.
9. What grounds for release from criminal liability do you know?
10. What judicial and non-judicial means of human rights in patient care protection do you know?

## **Content module 3.**

### **Legal regulation of certain types of medical activity**

**Theme.** *Legal regulation of family medicine in Ukraine. Folk medicine (healing) under the laws of Ukraine*

**Objective:** studying basic legal aspects of family medicine, legal status of a family doctor, clarifying legal basics of healing.

#### **A student should know:**

- National laws, which regulate family medicine;
- Legal status of a family doctor;
- Legal status of a family clinic;
- Legal regulation of folk medicine.

#### **A student should be able to:**

- Analyze current laws in the sphere of family medicine, folk medicine and healing;
- Prepare drafts of necessary legal documents;
- Research the role and importance of family medicine with the view of Ukraine-EU Association agreement.

#### **Plan of the class**

1. General characteristics of family medicine: notion, principles, importance and international standards.
2. Legal regulation of family medicine in Ukraine.



3. Legal status of a family clinic.
4. Legal status of a family doctor.
5. Legal regulation of folk medicine and healing in Ukraine.
6. Grounds for practicing folk medicine and healing in Ukraine.
7. Legal status of subjects, who are practicing healing and folk medicine.
8. Legal liability in the sphere of folk medicine and healing.

### **Self-control questions**

1. Characterize the term “family medicine”.
2. What principles of family medicine as they are foreseen in the international standards do you know?
3. Characterize the tasks of family medicine.
4. Name legal acts of your country, which regulate family medicine.
5. Describe legal status of a family clinic.
6. Characterize legal status of a family doctor.
7. What qualification requirements shall a family doctor meet?
8. Characterize the problems of family medicine development in Ukraine and your country.
9. Characterize legal basics of family medicine organization.
10. Characterize the system of family medicine in your country.

***Theme. Legal regulation of prophylactics and treatment of infectious diseases.***

***Legal regulation of sanitary and epidemiological welfare in Ukraine***

**Objective:** studying international and regional standards and national laws, which regulate the issues of prophylactics and treatment of infectious diseases, analyzing the aspect of sanitary and epidemiological protection in Ukraine.

**A Student should know:**

- List of key legal acts on the topic;
- International and regional standards on the topic;
- Legal aspects of prophylactics;
- Legal regulation of compulsory treatment of infectious diseases.

**A student should be able to:**

- Analyze current laws in the sphere of health care;
- Characterize international and regional standards in the sphere of health care;
- Prepare necessary legal documents;

**Plan of the class**

1. Legal regulation of the protection of the population from infectious diseases.
2. Legal status of medico-legal relations subjects in conditions of infectious diseases treatment.
3. Organization of prophylactics and treatment of infectious diseases in Ukraine.
4. Legal regulation of prophylactic vaccinations.
5. Legal aspects of fighting tuberculosis.

6. General characteristics of legal regulation in the sphere of HIV/AIDS treatment. International standards and national laws.
7. Peculiarities of the legal status of persons living with HIV/AIDS. Legal status of medical professionals, who are dealing with HIV/AIDS patients.

### **Self-control questions**

1. Name at least 4 legal acts of your country, which regulate the relations connected with protection of the population from infectious diseases.
2. What principles of prophylactics of infectious diseases are foreseen by Ukrainian legislation?
3. Characterize patient's rights in the course of vaccination.
4. Characterize the responsibilities of a patient in the course of vaccination.
5. Characterize the guarantees of professional activity of physicians working in the sphere of protection of the population from infectious diseases.
6. Characterize relevant state programs of Ukraine and your country directed at fighting HIV/AIDS, hepatitis.
7. Describe a legal status of a physician, who is dealing with patients, suffering from tuberculosis.
8. Describe the features and principles of voluntary screening of HIV.
9. Who is entitled to get familiar with the results of HIV screening?
10. Characterize the rights of patient suffering from tuberculosis.

***Theme. Donation under the laws of Ukraine. Legal regulation of reproductive health and reproductive technologies in Ukraine. Gender adjustment***

**Objective:** formation of basic knowledge as regards to reproductive health of the population and reproductive technologies, studying legal basics of donation in Ukraine.

**A student should know:**

- Key legal acts on the topic.
- International and regional standards in the sphere of health care.
- The notion and types of donation in Ukraine.
- Legal aspects of different types of donation in Ukraine.

**A student should be able to:**

- Analyze current laws in the sphere of health care;
- Characterize international and regional standards in the sphere of health care;
- Differentiate various types of donation and their legal regulation.
- Prepare necessary legal documents.

**Plan of the class**

1. Legal regulation of assisted reproductive technologies application in Ukraine. Legal status of a married couple in the course of assisted reproductive technologies application.

2. Ethical and legal aspects of surrogate motherhood. Features of a legal status of a surrogate mother.
3. Notion and types of donation under the laws of Ukraine.
4. Peculiarities of reproductive cells application.
5. Legal regulation of organization of blood and its components donation.
6. Legal regulation of organ and other anatomic materials donation.
7. Sex reassignment: legal regulation and law practice. Right to gender identity.

### **Self-control questions**

1. Define the term “assisted reproductive technologies”.
2. Enumerate human rights in the sphere of assisted reproductive technologies application.
3. Describe a human right to donation of reproductive technologies.
4. Characterize legal grounds for artificial insemination.
5. Describe the issues of parenthood under the laws of your country.
6. Characterize a procedure of application of assisted reproductive technologies in your country.
7. Explain the notion surrogate motherhood.
8. Explain the essence of reproductive technologies in the sphere of surrogate motherhood.
9. Define a legal status of a surrogate mother.
10. Characterize legal aspects of sex reassignment in your country.

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

**Objective:** study legal aspects of intellectual property protection in the sphere of health care, learn legal basics of providing the population with medicines and medical equipment.

**A student should know:**

- List of key legal acts on the topic;
- Relevant international and regional standards;
- Legal basics of the intellectual property protection;
- Legal aspects of pharmaceutical activity;

**A student should be able to:**

- Analyze relevant laws in the sphere of human rights in patient care;
- Characterize relevant international and regional standards of human rights in patient care;
- Analyze the essence of the intellectual property right;
- Provide for the realization of the rights of subjects of pharmaceutical activity.

**Plan of the class**

1. Legal basics of pharmacy in Ukraine.
2. Notion and legal status of medical professionals.
3. Legal aspects of carrying out pharmaceutical practice.
4. Advertisement of medicines.

5. Legal liability of pharmaceutical professionals for the professional violations.
6. Creation, manufacturing and sales of medicines: legal aspects
7. Patenting of medicines.
8. The notion and legal regime of generic drugs. Grounds for compulsory licensing of patents for medicines.
9. State control over the quality of medicines.
10. Legal guarantees for the providing the certain categories of people with drugs and medical equipment.

### **Self-control questions**

1. Elucidate legal status of pharmaceutical professionals.
2. Characterize basic requirements for the attestation of medical professionals.
3. What legal conditions should be met to carry out pharmaceutical activity?
4. Which legal acts of your country regulate the issues sales of medicines?
5. Which state body of your country is responsible for state control over drugs circulation?
6. Characterize the procedure of obtaining a patent for medical drugs.
7. Characterize the conditions for manufacturing of legal drugs.
8. Explain a legal regime of generic drugs.
9. Explain the essence of clinical trials of medicines.

10. Characterize legal conditions for importing medical drugs in your country.

**Theme.** *Legal regulation of psychiatric care. Legal regulation of providing medical care to the vulnerable groups of the population*

**Objective:** learning of the national laws and international and regional standards, which regulate certain aspects of human rights (respecting human rights in the sphere of psychiatry, drug abuse, problems of people living with disabilities, protection of the rights of minors), studying the mechanisms for the human rights in patient care protection.

**A student should know:**

- List of key legal acts on the topic;
- International and regional standards in the sphere of health care and human rights;
- Notion, features and types of psychiatric care;
- Peculiarities for the realization of the rights of people, belonging to vulnerable groups;
- Procedure for the realization of children' rights.

**A student should be able to:**

- Analyze relevant laws in the sphere of health care;
- Characterize international and regional standards of human rights in patient care;



- Describe a procedure of providing psychiatric care on a voluntary basis and a compulsory care,
- Characterize the peculiarities of the rights of persons with disabilities realization.
- Explain the mechanisms of realization of the rights of children.

### **Plan of the class**

1. Problems of social and legal protection of persons with disabilities in Ukraine.
2. Legal regulation of carrying out preventive measures as regards to prophylactics and treatment of chronic alcoholism, drug abuse and other socially dangerous diseases. State policy in the sphere of tobacco fighting.
3. Peculiarities of children' rights realization in Ukraine.
4. Legal regulation of psychiatric care provision.
5. Legal status of medical professionals, who are dealing with mentally ill patients.
6. Legal regulation of providing medical care to marginalized groups.

### **Self-control questions**

1. Give a definition of the term “person with disability”.
2. Describe the grounds for declaring a patient certain level of disability.
3. Explain a procedure of compulsory psychiatric care provision.

4. Characterize the grounds for a termination of compulsory psychiatric care.
5. Characterize legal status of a psychiatric patient.
6. Describe the peculiarities of children rights realization in the sphere of health care.
7. Explain the state policy of your state in the sphere of tobacco fighting.
8. Enumerate at least 6 rights of children in the sphere of health care.
9. What preventive measures are taken by state bodies of your country in relation to fighting chronic alcoholism and drug abuse?
10. Explain the procedure of providing psychiatric care on a voluntary basis.

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

**Objective:** studying international regional standards and national laws, which regulate palliative care, learning the peculiarities of hospices functioning and mechanisms of palliative care provision, clarifying a legal status of doctor and patient as well as other subjects in the course of palliative care provision.

**A student should know:**

- List of key legal acts on the topic;
- International and regional standards in the sphere of health care;
- Legal status of medico-legal relations subjects in the course of palliative care provision.

- Legal aspects of palliative care provision.

**A student should be able to:**

- Analyze relevant laws in the sphere of health care;
- Characterize international and regional standards in the sphere of health care;
- Explain legal status of a physician, who is providing palliative care;
- Provide for the protection of human rights in palliative care;
- Prepare necessary legal documents.

**Plan of the class**

1. General characteristics of palliative care provision in Ukraine.
2. International and regional standards, which regulate palliative care.
3. Procedure and peculiarities of palliative care provision in Ukraine.
4. Legal status of medico-legal relations subjects in the course of palliative care provision.
5. Legal status of a hospice.

**Self-control questions**

1. Provide a definition of the term “hospice”.
2. Provide a legal definition of the term “palliative care”.
3. Enumerate the main components of palliative care.
4. Describe legal grounds for palliative care provision.

5. Enumerate patient rights in the sphere of palliative care.
6. Describe a legal status of a medical professional, who is providing palliative care.
7. What the patient right to respect of his dignity mean.
8. Enumerate at least 4 examples of human rights in the sphere of palliative care violations.
9. What international standards regulate the issues of palliative care provision?
10. Characterize the system of palliative care in your country.

**Theme.** *Legal regulation of cosmetology and sports and fitness activity (sports medicine). Sanatorium and spa activity. Medical tourism.*

**Objective:** studying international and regional standards and national laws, which regulate the procedures of cosmetic care provision, learn the procedure of providing resort treatment and legal basics of medical tourism.

**A student should know:**

- List of key legal acts on the topic;
- Legal basics of cosmetic care provision;
- Legal aspects of medical tourism;
- Procedure of conducting resort medical treatment.

**A student should be able to:**

- Analyze relevant laws in the sphere of health care;
- Prepare necessary legal documents.

- Characterize international and regional standards in the sphere of health care;

### **Plan of the class**

1. Legal regulation of plastic and reconstructive surgery.
2. The notion of cosmetology and its legal regulation.
3. International and regional standards in the sphere of sports medicine.
4. Cosmetic services and peculiarities of their provision.
5. Organizational aspects of cosmetic clinics functioning.
6. Legal regulation of fitness-centers and other sports facilities functioning
7. Commercial activity in the sphere of beauty and sport.
8. Peculiarities of medical tourism legal regulation.

### **Self-control questions**

1. Name several international standards in the sphere of sports medicine and cosmetology.
2. Describe a legal status of a doctor, who can provide cosmetic surgery services.
3. Describe the functions of a cosmetic clinic.
4. What is medical tourism?
5. What types of medical tourism do you know?
6. What is sport medicine?
7. Describe the peculiarities of resort medical care provision.

8. Describe the peculiarities of medical rehabilitation procedures.
9. Characterize legal status of the sports health care facility.
10. What patient's rights in the sphere of cosmetology and sports medicine do you know?

# The practical work

## Theme. Legal foundations of bioethics



### Plan

- 1. Ethics and deontology in medical practice.*
- 2. Bioethical law as a science.*
- 3. Bioethical rights and freedoms.*
- 4. Guarantees bioethical rights and freedoms.*
- 5. International legal standards in the field of bioethics.*

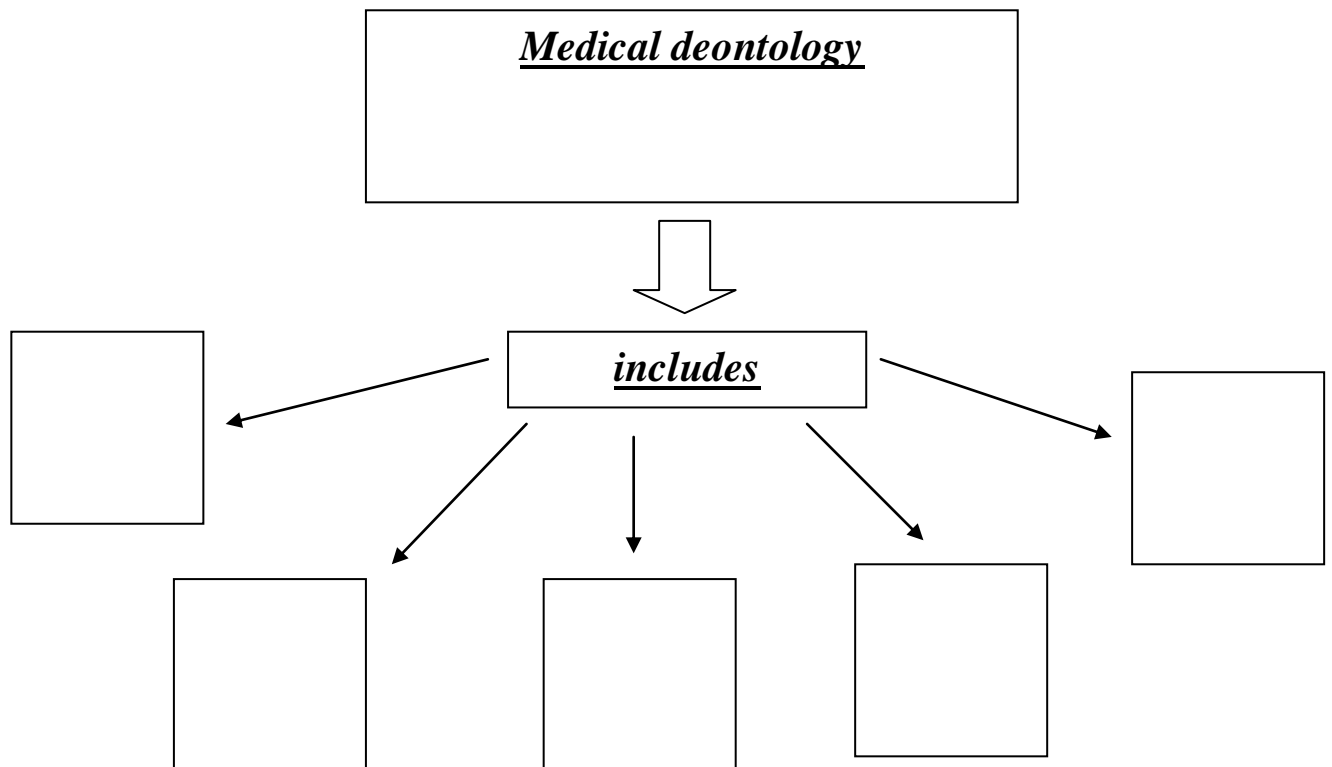
Exercise 1. Define the term:

**Medical ethics (medical deontology) -**

**Deontology -**

**Euthanasia -**

Exercise 2. Fill in the scheme.



Exercise 3. Write duties doctor to the patient.

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Exercise 4 . Describe according to the law, the right to privacy and information.

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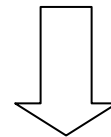
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Exercise 5 . Fill in the scheme.

**Organ and tissue removal from living donors  
for transplantation purposes**




**General rule:**

Exercise 6. Define the term, according to the law of Ukraine «On the prohibition of the reproductive cloning of human beings»:

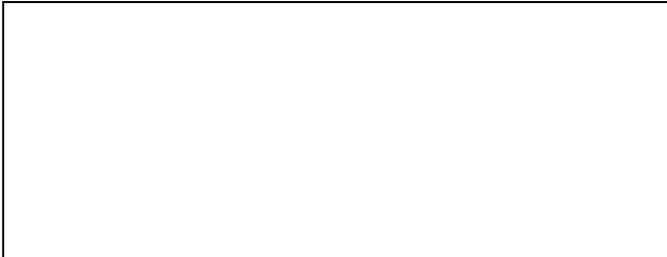
- human cloning –
- human embryo –
- Euthanasia -

**Exercise 7. Fill in the scheme.**

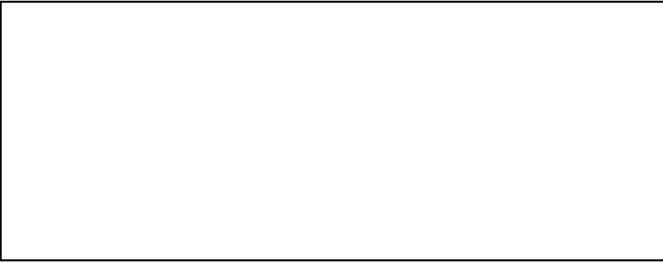
**Euthanasia**

**What is it?** → 

**Euthanasia**

**The forms** → 

**Euthanasia**

**Can be** → 

**Exercise 7. Solve a situational problem.**

The young couple had one child. A family would like to raise twins. The couple decided to clone their newborn baby. Ukrainian company with foreign capital share activity was scientific development of reproductive technologies, signed a contract with the young couple clone their child.

*Is it legal? What bioethical issues you see in this situation?*

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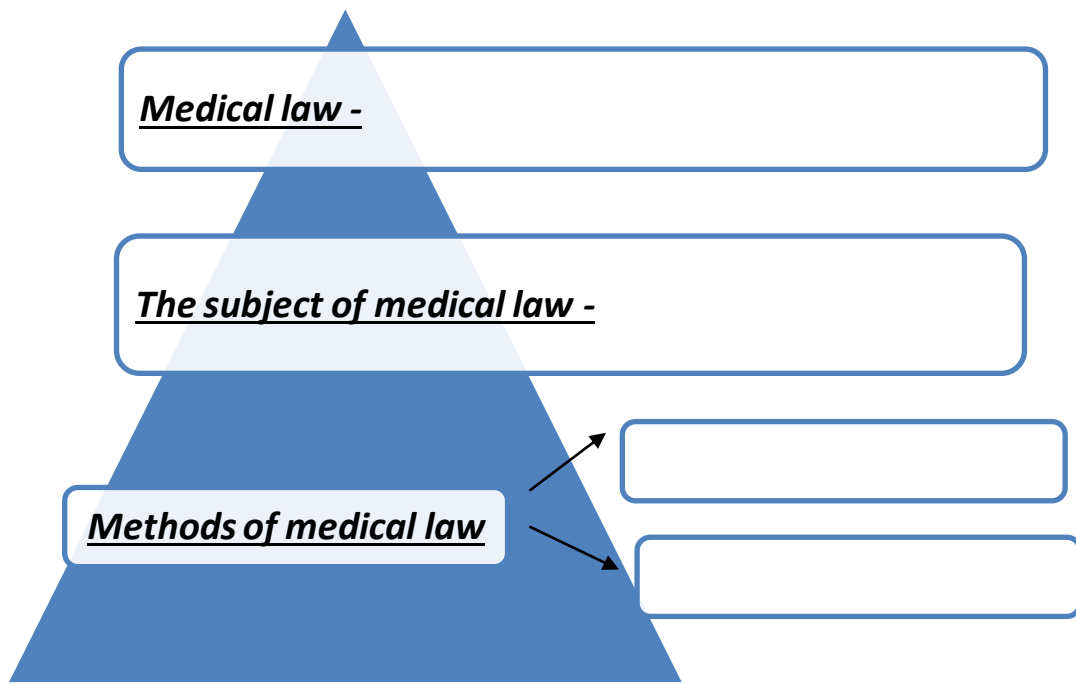
# **Theme. Medical law in the system of medical education**



## **Plan**

- 1. Medical law as an academic discipline.***
- 2. Relations in the health sector: the concept and composition.***
- 3. Subjects of legal relations in the sphere of health.***
- 4. Objects relations in health care.***
- 5. Sources of law governing relations in the health sector.***

Exercise 1. Fill in the scheme.



Exercise 2. Describe principles of medical law.

Principles of Medical Law:

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Exercise 3. Fill in the scheme.



What is it? →

**Group of  
medical  
relations:**



**Exercise 4. Describe the group of legal facts.**

**Legal facts are divided into:**

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**Exercise 5. Write Source of medical law**

**SOURCE OF MEDICAL LAW**


**Exercise 6.**

**Classification of sources of health law:**

- 1.
- 2.
- 3.
- 4.

**Exercise 7. Describe the legislative base of Ukraine, which regulates health.**

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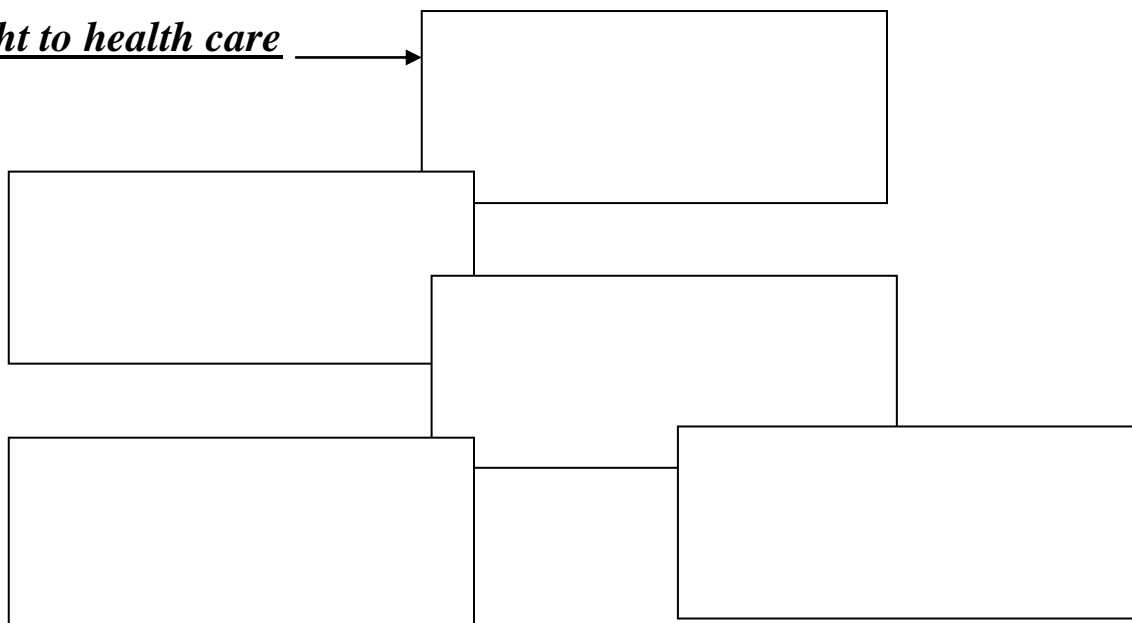
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**Exercise 8. The right to health care (the law «The Civil Code of Ukraine»)**

**The right to health care**



**Exercise 9. Give the characteristic of the Laws of Ukraine:**

**1. Law of Ukraine "Basic Laws of Ukraine on Health Care ":**

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**2. Law of Ukraine "On the transplantation of organs and other anatomical human materials":**

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**3. Law of Ukraine "On the donation of blood and blood components":**

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**4. Law of Ukraine "On Psychiatric Care":**

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**5. Law of Ukraine "On the Fight against TB ":**

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**6. Law of Ukraine «On the prohibition of the reproductive cloning of human beings»:**

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**Theme. *Legal regulation of health in Ukraine.***  
***Medical care and services: legal nature and characteristics under the laws of Ukraine***



**Plan**

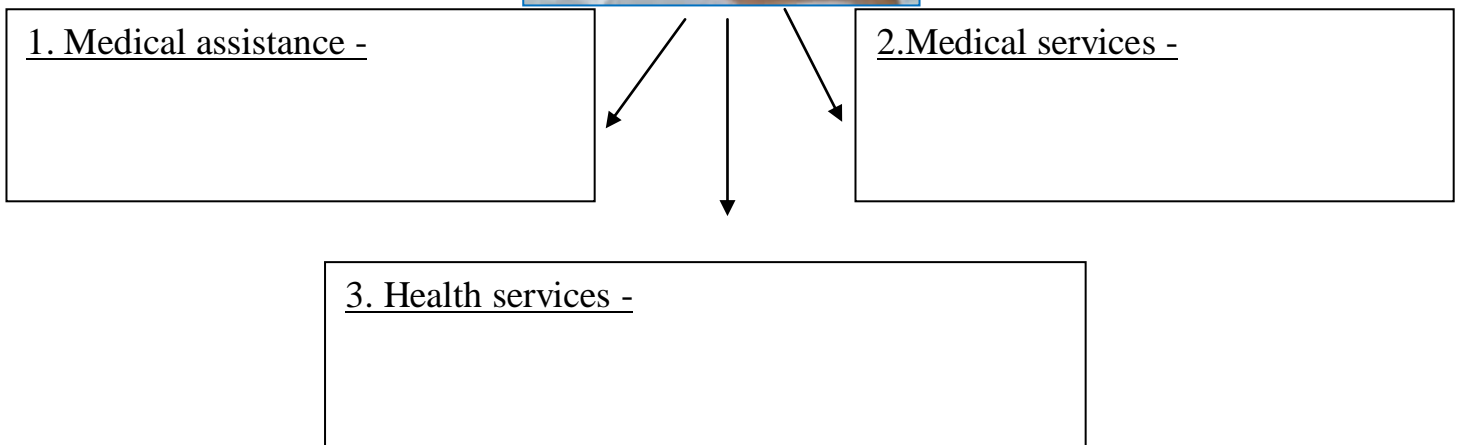
- 1. Organization, management and regulation of health care.*
- 2. Concept and types of medical care (Medicare) under the laws of Ukraine.*
- 3. State control and supervision in the field of health.*
- 4. State accreditation of health institutions and licensing business of medical practice.*
- 5. Concepts are a treating doctor, medical secret, medical interference.*



**Exercise 1. Fill the table.**

<i>Terms</i>	<i>Definitions</i>
<b>Health</b>	
<b>Health institution</b>	
<b>Network of health care institutions</b>	
<b>Patient</b>	
<b>Treating doctor</b>	
<b>Medical secret</b>	

**Exercise 2. Write definitions, according to the laws of Ukraine.**



Exercise 3. Concept and types of medical care under the laws of Ukraine.

<i>Types of medical care</i>	<i>Definitions</i>
<b>1. Urgent (emergency) Medicare</b>	
<b>2. Primary health care</b>	
<b>3. Secondary (specialized) Medicare</b>	
<b>4. Tertiary (highly specialized)</b>	
<b>5. Palliative care</b>	
<b>6. Medical rehabilitation</b>	

Exercise 4. Write system standards for health protection in Ukraine.



**Exercise 5. Solve situational problems.**

Ivanova Olga works as a nurse at the hospital. It is registered as a business entity, rents a room in the same hospital and performs services for body massage.

*Give a legal assessment of the above situation. Olga is necessary to obtain a license to provide services in a body massage?*

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**Exercise 6. Fill the table «Quality of care and public health institutions accreditation, licensing of medical practice»:**

<i>Terms</i>	<i>Definitions</i>
<b>1. The quality of Medicare</b>	
<b>2. Assessment of quality of Medicare</b>	
<b>3. Accreditation of medical establishment</b>	
<b>4. Licensing of medical activity</b>	
<b>5. A license to realization of medical practice</b>	

*Exercise 7. Describe a scheme, the process of licensing of medical practice in Ukraine.*

*Licensing*

# **Theme. Legal status of subject of medical legal relationships**



## **Plan**

- 1. International standard - legal acts in the field of health.***
- 2. International legal regulation of human rights.***
- 3. International Human Rights Law and the personal freedom of health professionals.***
- 4. The right and duties doctor in Ukraine.***
- 5. Legal regulation of rights and duties for patients: national acts.***

**Exercise 1.** What are the sources (international organizations), establishing international legal norms in the field of Health and publish documents.

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**Exercise 2.** Write international - legal documents that regulate the rights of man and his health.

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**Exercise 3.** Fill in the scheme.

The International Charter of Human Rights



consists of five documents



What are the documents?

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_

**Exercise 4.** Give a description of the "Declaration on human rights and personal freedom of health care providers."

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**Exercise 5. Describe the regulatory documents governing the rights and obligations of the physician in Ukraine.**



**Rights and duties of the doctor are regulated by the following regulations (in Ukraine):**







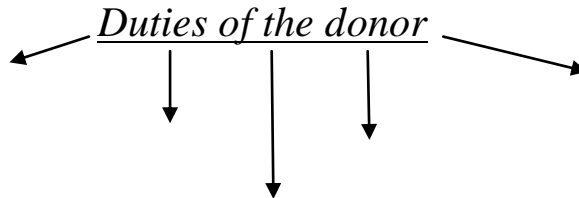
# **Theme. Legal regulation of certain types of medical activities**



## **Plan**

- 1. Legal regulation of the donation, in particular transplantation in Ukraine.***
- 2. Legal regulation of psychiatric care.***
- 3. Telemedicine - a new form of health care.***

**Exercise 1. Describe the duties of donor**



**Exercise 2. Describe the procedure for making blood and blood components.**

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**Exercise 3. Give the definition of:**

<i>Terms</i>	<i>Definitions</i>
1. Transplantation	
2. Anatomical materials	
3. Donor	
4. Recipient	
5. Homotransplantations	
6. Bioimplants	
7. Xenografts (Engrafts)	
8. Fetal materials	

**Exercise 4. Fill the table «About Psychiatric Care»:**

<i>Definitions</i>	<i>Terms</i>
Disorders of mental activity, recognized in accordance with such force in Ukraine international statistical classification of diseases, injuries and causes of death →	
A disorder of mental activity (dizziness, breach of perception, thought, will, emotions, intellect or memory), which eliminates a person's ability to adequately understand the surrounding reality, his mental state and behavior →	
A set of specific measures aimed at mental health examination of persons on the grounds and in the manner prescribed by this Law and other laws, prevention,	

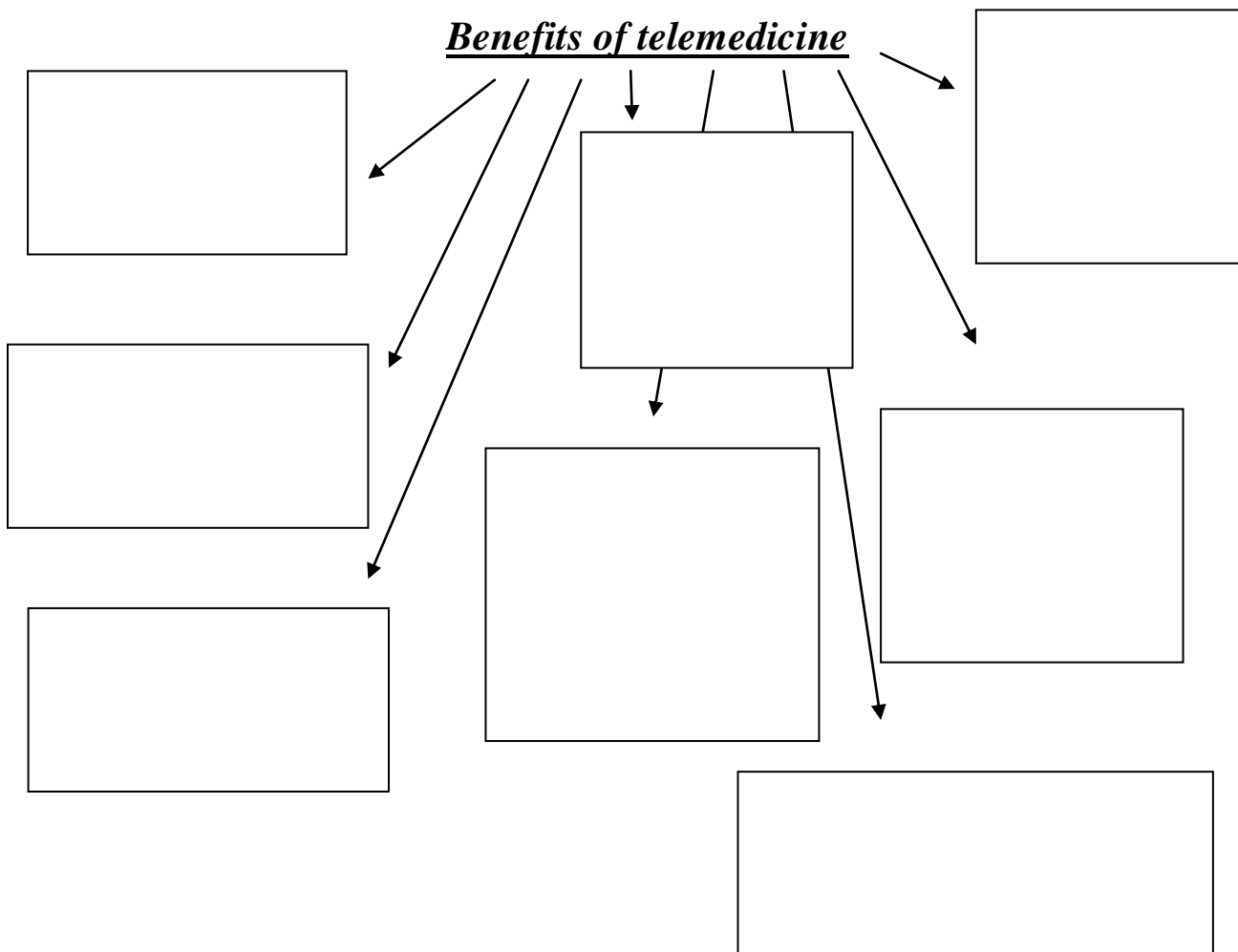
diagnosis, mental disorders, treatment, supervision, care and medical and social rehabilitation of persons suffering from mental disorders →	
A neuropsychiatric, a narcological, or other specialized institutions, centers, branches that provide psychiatric help →	
Mental health care, which includes a survey of mental health people on the grounds and in the manner prescribed by this Law and other laws, prevention, diagnosis of mental disorders, treatment, supervision, care, medical and social rehabilitation of persons suffering from mental disorders in outpatient settings →	
Mental health care, which includes a survey of mental health people on the grounds and in the manner prescribed by this Law and other laws, the diagnosis of mental disorders, treatment, supervision, care, medical and social rehabilitation of persons suffering from mental disorders, and provided in a hospital more than 24 consecutive hours →	

**Exercise 5. Describe the rights of people receiving psychiatric care.**

**Persons who provided psychiatric care are entitled to:**

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.

**Exercise 6. Fill in the scheme.**



## **LIST OF QUESTIONS FOR STUDENTS, WHO ARE PREPARING FOR THE DISCIPLINE**

1. The legal nature of medical law (the branch of law, the institution of law, branch of legislation).
2. Medical Law of Ukraine as a legal phenomenon: concepts, tasks, object of legal regulation.
3. Medico-legal relationship: 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 sphere of health care and human rights, which contain binding rules and principles ("hard law") (including the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social and Cultural Rights, Convention on the Rights of the Child, the Convention on the Rights of Persons with Disabilities)
10. Regional acts in the sphere of health care and human rights, which contain binding rules and principles ("hard law") (including the European Convention for the Protection of Human Rights and Fundamental Freedoms, the European Social Charter, the European Convention on Human Rights and Biomedicine).
11. International acts in the sphere of health care and human rights, that contain non-binding (recommendatory) standards and principles ("soft law") (eg, 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 the European Charter of Patients' Rights, the 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 sphere of health care and human rights.

15. The rights of medical professionals fixed in the international standards in the sphere of health care and human rights.

16. Rights of patients under regional standards in the sphere of health care and human rights.

17. Rights of medical professionals under regional standards in the sphere of health care and human rights..

18. Place and importance of European Union laws in the system of regional standards in 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 health care legislation of Ukraine and documents of national 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 sphere 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, subjects, 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 liability insurance of medical professionals.
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 sphere 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 question 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.

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 sphere 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. The legal status of the doctor in charge under the national laws.
60. Concept and types of procedures and mechanisms for the protection of rights of medico-legal relations subjects.
61. The forms of protection of human health relations: concept, types, means of exercise.
62. The judicial form of protection of the rights of medico-legal relations subjects in constitutional and administrative proceedings.
63. The judicial form of protection of the rights of medico-legal relations subjects in civil proceedings.
64. The judicial form of protection of the rights of medico-legal relations subjects in criminal proceedings.
65. Extrajudicial form of protection of the rights of medico-legal relations subjects: 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 subjects.
68. Civil liability in the sphere 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 decisions in medical cases.

75. International forms and means of medico-legal relations subjects' 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. The concept, types and importance of medical examinations in Ukraine.

80. The 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: complete 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 affairs.

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 subjects.
93. Features of clinical expert commissions' operation.
94. Features of legal regulation of dental tourism.
95. Dental care in Ukraine: legal regulation.
96. The legal status of patients in the field of dentistry.
97. The 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 sphere of dentistry.
103. General characteristics of Family Medicine: concepts, principles, values and legal regulation.
104. The legal status of clinic of general practice - family medicine.
105. The legal status of the family doctor.
106. Concept and types of donation under the laws of Ukraine.
107. The concept and principles of blood and its components donation.
108. Legal regulation of human organs and other anatomical materials donation.
109. The legal regulation of reproductive cell donation in Ukraine.

110. International and regional standards in the sphere of health care aimed at protection the population from infectious diseases, including transmitted sexually diseases.

111. Legal regulation of prevention and treatment of infectious diseases, including those that are sexually transmitted in Ukraine.

112. The legal status of medico-legal relations subjects in terms of treatment of infectious diseases, including sexually transmitted diseases.

113. The 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 sphere 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 sphere 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, the object of which is a medicine.
132. The 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 sphere of health care.
138. Legal regulation of providing medical care to persons with disabilities in Ukraine.
139. Legal regulation of providing medical care to persons, who are kept in detention.
140. Legal regulation of providing medical care to the elderly persons.

## Information resources

### International and regional standards

1. UN General Assembly, Convention on the Rights of the Child, Resolution 44/25, A/RES/44/25 (November 20, 1989).  
<http://www.ohchr.org/EN/ProfessionalInterest/Pages/CRC.aspx>.
2. UN General Assembly, International Covenant on Civil and Political Rights, A/RES/21/2200 (December 16, 1966).  
<http://www.ohchr.org/EN/ProfessionalInterest/Pages/CCPR.aspx>.
3. UN General Assembly, International Covenant on Economic, Social, and Cultural Rights, A/RES/21/2200 (December 16, 1966).  
<http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx>.
4. UN General Assembly, International Convention on the Elimination of all forms of Racial Discrimination, Resolution 2106 (XX), A/RES/20/2106 (December 21, 1965).  
<http://www.ohchr.org/EN/ProfessionalInterest/Pages/CERD.aspx>.
5. UN General Assembly, Convention on the Elimination of all Forms of Discrimination Against Women, Resolution 34/180, A/RES/34/180 (December 18, 1979). <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CEDAW.aspx>.
6. UN General Assembly, Convention of the Rights of Persons with Disabilities, Resolution 61/106, A/RES/61/106 (December 13, 2006). <http://www.un.org/disabilities/convention/conventionfull.shtml>.
7. Council of Europe, Convention for the Protection of Human Rights and Fundamental Freedoms.  
[conventions.coe.int/Treaty/en/Treaties/Html/005.htm](http://conventions.coe.int/Treaty/en/Treaties/Html/005.htm).



8. Council of Europe, European Social Charter (1996 revised edition). [conventions.coe.int/Treaty/EN/Treaties/Html/035.htm](http://conventions.coe.int/Treaty/EN/Treaties/Html/035.htm).
9. Active Citizen Network, European Charter of Patients' Rights (2002). [www.eesc.europa.eu/self-and-coregulation/documents/codes/private/085-private-act.pdf](http://www.eesc.europa.eu/self-and-coregulation/documents/codes/private/085-private-act.pdf)
10. Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997). <http://conventions.coe.int/Treaty/EN/Treaties/Html/164.htm>.
11. European Court of Human Rights. Case of Mehmet Senturk and Bekir Senturk v. Turkey (2013). Available at: <http://hudoc.echr.coe.int/eng?i=001-118722>
12. European Court of Human Rights. Case of Z. v. Finland. Available at: <http://hudoc.echr.coe.int/eng?i=001-58033>
13. European Court of Human Rights. Case of V.C. v. Slovakia. Available at: <http://hudoc.echr.coe.int/eng?i=001-107364>
14. European Court of Human Rights. Case Arskaya v. Ukraine. Available at: <http://hudoc.echr.coe.int/eng?i=001-138590>
15. European Court of Human Rights. Case VO v. France. Available at: <http://hudoc.echr.coe.int/eng?i=001-61887>
16. European Court of Human Rights. Case CSOMA v. Romania. Available at: <http://hudoc.echr.coe.int/eng?i=001-115862>
17. European Court of Human Rights. Case G.B. and R.B. v. Moldova. Available at <http://hudoc.echr.coe.int/eng?i=001-115395>