

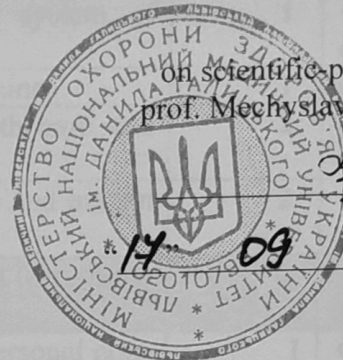
DANYLO HALYTSKYI LVIV NATIONAL MEDICAL UNIVERSITY

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

“Approved”

First vice-rector

on scientific-pedagogical work
prof. Mechyslav R. Gzhegotskyi

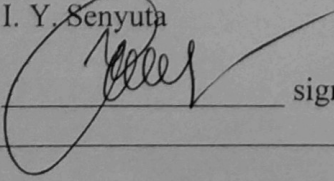
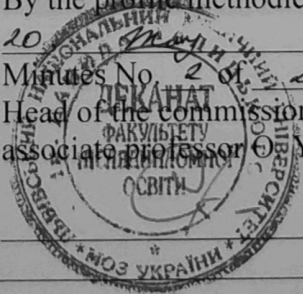


2021

**METHODOLOGICAL RECOMMENDATIONS FOR SELF-RELIANT WORK
ON THE ACADEMIC DISCIPLINE “MEDICAL LAW”**

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

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

<p>Discussed and adopted on the meeting of the Department <u>30, April</u> 2021 Minutes No. <u>1</u> of <u>30.04.2021</u> Head of the Department, professor I. Y. Senyuta  signature</p>	<p>Approved By the profile methodic commission <u>20.05.2021</u> 2021 Minutes No. <u>2</u> of <u>20.05.2021</u> Head of the commission, dean of the FPGE, associate professor O. Y. Sichkoriz  signature</p>
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Self-reliant work of students and its control

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

The topicality of the issues, which are studied within the discipline, their role and importance for the preparation of future medical professionals, a significant amount of questions, which should be learned for a comprehensive preparation of a professional, require that a number of topics should be studied by students themselves within extracurricular work.

A student should study the questions elucidated in the plan of the class using the literature resources provided in each topic and check the level of knowledge using self-control questions.

Content module 1. Medical Law as a Legal Phenomenon

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

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

Student shall 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 Ukrainian legislation in the field of health care

Student shall be able to:

- Analyze relevant statutes in the field of health care;
- Develop necessary notion and categorical apparatus;
- Characterize the 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.

Recommended literature

Basic literature

1. Miola, José and Foster, Charles, Who's in Charge? The Relationship between Medical Law, Medical Ethics and Medical Morality (November 7, 2014). University of Leicester School of Law Research Paper No. 14-28. Available at SSRN: <http://ssrn.com/abstract=2520488> or <http://dx.doi.org/10.2139/ssrn.2520488>

2. Byrne I., Ezer T. Cohen J. Overall. J, Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. – Lviv. LOBF Publisher’s “Medicine and Law, 2012 – 497 pages.

3. Health and Human Rights: A Resource Guide. Available at: <http://fxb.harvard.edu/health-and-human-rights-resource-guide/>

Additional literature

1. Beermann, Jack Michael, Government's Obligation to Provide for the Health, Safety and Welfare of Its Citizens (March 18, 2014). Boston Univ. School of Law, Public Law Research Paper No. 14-15. Available at SSRN:<http://ssrn.com/abstract=2410978> or <http://dx.doi.org/10.2139/ssrn.2410978>

2. Cortez, Nathan, Patients without Borders: The Emerging Global Market for Patients and the Evolution of Modern Health Care. Indiana Law Journal, Vol. 83, 2008; SMU Dedman School of Law Legal Studies Research Paper No. 00-24. Available at SSRN: <http://ssrn.com/abstract=982742>

3. Golynger, Oxana, Patient Mobility and Healthcare in the EU (November 24, 2014). University of Leicester School of Law Research Paper No. 14-33. Available at SSRN: <http://ssrn.com/abstract=2529941> or <http://dx.doi.org/10.2139/ssrn.2529941>

4. Gostin, Lawrence O., A Theory and Definition of Public Health Law (September 17, 2008). Lawrence O. Gostin, PUBLIC HEALTH LAW POWER, DUTY, RESTRAINT, Revised & Expanded Second Edition, University of California Press/ Milbank Memorial Fund, 2008; Georgetown University/O'Neill Institute for National & Global Health Law Scholarship Research Paper No. 8. Available at SSRN: <http://ssrn.com/abstract=1269472>

5. Leonard, Elizabeth Weeks, The Public's Right to Health: When Patient Rights Threaten the Commons (August 18, 2008). Washington University Law Review, Vol. 86, p. 1335, 2009. Available at SSRN:<http://ssrn.com/abstract=1234542>

Topic 2. Legal regulation of the health care system in Ukraine

Objective: to study the notion and categorical apparatus in the field of medical law, sources and types of medical law, trends of law-making in the field of health care. Analysis of the national laws in the field of health care.

Student shall know:

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

Student shall be able to:

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

Plan of the class

1. History of legal regulation of the health care system in Ukraine.
2. General characteristics of the legislation in the field 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.

Recommended literature

Basic literature

1. Byrne I., Ezer T. Cohen J. Overall. J, Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. – Lviv. LOBF Publisher’s “Medicine and Law, 2012 – 497 pages.
2. Health and Human Rights: A Resource Guide. Available at: <http://fxb.harvard.edu/health-and-human-rights-resource-guide/>
3. Beletsky, Leo and Ezer, Tamar and Overall, Judith and Byrne, Iain and Cohen, Jonathan, Advancing Human Rights in Patient Care: The Law in Seven Transitional Countries (January 31, 2013). Open Society Foundations, 2013; Northeastern University School of Law Research Paper No. 125-2013. Available at SSRN:<http://ssrn.com/abstract=2209796>

Additional literature

1. Matei, Emanuela, Economic and Social Patients' Rights in Cross Border Health Services: The Either or Fallacy (June 3, 2011). Lund Student EU Law Review, 2011. Available at SSRN: <http://ssrn.com/abstract=2296897>
2. Meier, Benjamin Mason and Bhattacharya, Dhruvajyoti, U.S. Health Care Reform as a Means to Realize the International Human Right to Health (2012). Debates on U.S. Health Care (Jennie Jacobs Kronenfeld, Wendy E. Parmet & Mark A. Zezza, eds.), (Sage, NY), 2012 Forthcoming. Available at SSRN:<http://ssrn.com/abstract=2095191>
3. Spronk, Sarah I., The Right to Health of the Child in International Health and Human Rights Law (June 8, 2012). Available at SSRN: <http://ssrn.com/abstract=2080018> or <http://dx.doi.org/10.2139/ssrn.2080018>
4. Gostin, Lawrence O. and Taylor, Allyn L., Global Health Law: A Definition and Grand Challenges. Public Health Ethics, Vol. 1, No. 1, pp. 53-63, 2008; Georgetown University

Topic 3. International standards in the field of health care and human rights.

Objective: to 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.

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.

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.

Recommended literature

Basic literature

1. Byrne I., Ezer T. Cohen J. Overall. J, Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. – Lviv. LOBF Publisher’s “Medicine and Law, 2012 – 497 pages.
2. Health and Human Rights: A Resource Guide. Available at: <http://fxb.harvard.edu/health-and-human-rights-resource-guide/>
3. Beletsky, Leo and Ezer, Tamar and Overall, Judith and Byrne, Iain and Cohen, Jonathan, Advancing Human Rights in Patient Care: The Law in Seven Transitional Countries (January 31, 2013). Open Society Foundations, 2013; Northeastern University School of Law Research Paper No. 125-2013. Available at SSRN:<http://ssrn.com/abstract=2209796>
4. Cohen, I. Glenn, Medical Tourism, Access to Health Care, and Global Justice (September 13, 2011). Virginia Journal of International Law, Vol. 52, 2011; Harvard Public Law Working Paper No. 11-23. Available at SSRN:<http://ssrn.com/abstract=1926880> or <http://dx.doi.org/10.2139/ssrn.1926880>

Additional literature

5. Matei, Emanuela, Economic and Social Patients' Rights in Cross Border Health Services: The Either or Fallacy (June 3, 2011). Lund Student EU Law Review, 2011. Available at SSRN: <http://ssrn.com/abstract=2296897>
6. Meier, Benjamin Mason and Bhattacharya, Dhrubajyoti, U.S. Health Care Reform as a Means to Realize the International Human Right to Health (2012). Debates on U.S. Health Care (Jennie Jacobs Kronenfeld, Wendy E. Parmet & Mark A. Zezza, eds.), (Sage, NY), 2012 Forthcoming. Available at SSRN:<http://ssrn.com/abstract=2095191>
7. Spronk, Sarah I., The Right to Health of the Child in International Health and Human Rights Law (June 8, 2012). Available at SSRN: <http://ssrn.com/abstract=2080018> or <http://dx.doi.org/10.2139/ssrn.2080018>
8. Gostin, Lawrence O. and Taylor, Allyn L., Global Health Law: A Definition and Grand Challenges. Public Health Ethics, Vol. 1, No. 1, pp. 53-63, 2008; Georgetown University O'Neill Institute for National & Global Health Law Scholarship Paper No. 14. Available at SSRN: <http://ssrn.com/abstract=1272424>
9. Raz, Joseph, Human Rights in the Emerging World Order (November 14, 2009). (2010) 1 Transnational Legal Theory 31–47. Columbia Public Law Research Paper No. 09-219; Oxford Legal Studies Research Paper No. 47/2009. Available at SSRN: <http://ssrn.com/abstract=1497055> or <http://dx.doi.org/10.2139/ssrn.1497055>

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 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>.

4. 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>.
5. 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>.
6. African Commission on Human and Peoples' Rights, African Charter on the Rights and Welfare of the Child (July 1, 1990). <http://www.achpr.org/instruments/child/>.
7. African Commission on Human and Peoples' Rights, Protocol to the African Charter on Human and Peoples' Rights: Establishment of the African Court on Human and Peoples' Rights (June 10, 1998). <http://www.achpr.org/instruments/court-establishment/>.
8. Africa Commission on Human and Peoples' Rights, Protocol to the African Charter on Human and Peoples' Rights: Rights of Women in Africa (November 7, 2003). <http://www.achpr.org/instruments/women-protocol/>.
9. Council of Europe, Convention for the Protection of Human Rights and Fundamental Freedoms. conventions.coe.int/Treaty/en/Treaties/Html/005.htm.
10. Council of Europe, European Social Charter (1996 revised edition). conventions.coe.int/Treaty/EN/Treaties/Html/035.htm.
11. Council of Europe, Framework Convention for the Protection of National Minorities (1995). conventions.coe.int/treaty/en/Treaties/Html/157.htm.
12. Organization of American States: Department of International Law, Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social, and Cultural Rights: 'Protocol San Salvador' (November 17, 1998). <http://www.oas.org/juridico/english/treaties/a-52.html>.
13. Organization of American States: Department of International Law, American Convention on Human Rights: 'Pact of San Jose, Costa Rica.' http://www.oas.org/dil/treaties_B-32_American_Convention_on_Human_Rights.htm.
14. Organization of American States: Department of International Law, Charter of the Organization of American States (1948). http://www.oas.org/dil/treaties_A-41_Charter_of_the_Organization_of_American_States.htm.
15. Active Citizen Network, European Charter of Patients' Rights (2002). www.eesc.europa.eu/self-and-coregulation/documents/codes/private/085-private-act.pdf

Topic 4. Regional standards in the sphere of health care and human rights.

Objective: to 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.

Student shall 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.

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 regional standards.
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?

Recommended literature

Basic literature

1. Byrne I., Ezer T. Cohen J. Overall. J, Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. – Lviv. LOBF Publisher's "Medicine and Law, 2012 – 497 pages.
2. Health and Human Rights: A Resource Guide. Available at: <http://fxb.harvard.edu/health-and-human-rights-resource-guide/>
3. Beletsky, Leo and Ezer, Tamar and Overall, Judith and Byrne, Iain and Cohen, Jonathan, Advancing Human Rights in Patient Care: The Law in Seven Transitional Countries (January 31, 2013). Open Society Foundations, 2013; Northeastern University School of Law Research Paper No. 125-2013. Available at SSRN:<http://ssrn.com/abstract=2209796>
4. Cohen, I. Glenn, Medical Tourism, Access to Health Care, and Global Justice (September 13, 2011). Virginia Journal of International Law, Vol. 52, 2011; Harvard Public Law Working Paper No. 11-23. Available at SSRN:<http://ssrn.com/abstract=1926880> or <http://dx.doi.org/10.2139/ssrn.1926880>

Additional literature

1. Matei, Emanuela, Economic and Social Patients' Rights in Cross Border Health Services: The Either or Fallacy (June 3, 2011). Lund Student EU Law Review, 2011. Available at SSRN: <http://ssrn.com/abstract=2296897>
2. Meier, Benjamin Mason and Bhattacharya, Dhruvajyoti, U.S. Health Care Reform as a Means to Realize the International Human Right to Health (2012). Debates on U.S. Health Care

(Jennie Jacobs Kronenfeld, Wendy E. Parmet & Mark A. Zezza, eds.), (Sage, NY), 2012 Forthcoming. Available at SSRN:<http://ssrn.com/abstract=2095191>

3. Spronk, Sarah I., The Right to Health of the Child in International Health and Human Rights Law (June 8, 2012). Available at SSRN: <http://ssrn.com/abstract=2080018> or <http://dx.doi.org/10.2139/ssrn.2080018>

4. Gostin, Lawrence O. and Taylor, Allyn L., Global Health Law: A Definition and Grand Challenges. Public Health Ethics, Vol. 1, No. 1, pp. 53-63, 2008; Georgetown University O'Neill Institute for National & Global Health Law Scholarship Paper No. 14. Available at SSRN: <http://ssrn.com/abstract=1272424>

5. Raz, Joseph, Human Rights in the Emerging World Order (November 14, 2009). (2010) 1 Transnational Legal Theory 31–47. Columbia Public Law Research Paper No. 09-219; Oxford Legal Studies Research Paper No. 47/2009. Available at SSRN: <http://ssrn.com/abstract=1497055> or <http://dx.doi.org/10.2139/ssrn.1497055>

Information resources

International and regional standards

1. 13, 2006). <http://www.un.org/disabilities/convention/conventionfull.shtml>.
2. African Commission on Human and Peoples' Rights, African Charter on the Rights and Welfare of the Child (July 1, 1990). <http://www.achpr.org/instruments/child/>.
3. African Commission on Human and Peoples' Rights, Protocol to the African Charter on Human and Peoples' Rights: Establishment of the African Court on Human and Peoples' Rights (June 10, 1998). <http://www.achpr.org/instruments/court-establishment/>.
4. Africa Commission on Human and Peoples' Rights, Protocol to the African Charter on Human and Peoples' Rights: Rights of Women in Africa (November 7, 2003). <http://www.achpr.org/instruments/women-protocol/>.
5. Council of Europe, Convention for the Protection of Human Rights and Fundamental Freedoms. conventions.coe.int/Treaty/en/Treaties/Html/005.htm.
6. Council of Europe, European Social Charter (1996 revised edition). conventions.coe.int/Treaty/EN/Treaties/Html/035.htm.
7. Council of Europe, Framework Convention for the Protection of National Minorities (1995). conventions.coe.int/treaty/en/Treaties/Html/157.htm.
8. Organization of American States: Department of International Law, Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social, and Cultural Rights: 'Protocol San Salvador' (November 17, 1998). <http://www.oas.org/juridico/english/treaties/a-52.html>.
9. Organization of American States: Department of International Law, American Convention on Human Rights: 'Pact of San Jose, Costa Rica.' http://www.oas.org/dil/treaties_B-32_American_Convention_on_Human_Rights.htm.
10. Organization of American States: Department of International Law, Charter of the Organization of American States (1948). http://www.oas.org/dil/treaties_A-41_Charter_of_the_Organization_of_American_States.htm.
11. Active Citizen Network, European Charter of Patients' Rights (2002). www.eesc.europa.eu/self-and-coregulation/documents/codes/private/085-private-act.pdf

Content module 2. Legal Status of Medico-Legal Relations' Participants and Mechanisms of their Rights Protection

Topic 5. The system of human rights in patient care. Personal non-proprietary rights

Objective: to form a basic knowledge as regards to the system of personal non-proprietary rights in the field of health care; to study the ways of exercising of these rights.

Student shall know:

- List of key legal acts on the topic;
- International and regional standards in the field of health care and human rights;
- List of key personal non-proprietary human rights in the field of health care;
- Peculiarities of the personal non-proprietary human rights in patient care exercising.

Student should be able to:

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

Self-control questions

1. Give the definition of the notion “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 as basic?
4. Which groups of the population should be entitled to certain kinds of privileges in the field 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-proprietary human rights?
10. Describe human right to respect of dignity in terms of human rights in patient care.

Recommended literature

Basic literature

1. Byrne I., Ezer T. Cohen J. Overall. J, Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. – Lviv. LOBF Publisher’s “Medicine and Law, 2012 – 497 pages.
2. Health and Human Rights: A Resource Guide. Available at: <http://fxb.harvard.edu/health-and-human-rights-resource-guide/>
3. Ayoub, Ahmed Yahya, Do Not Resuscitate: An Argumentative Essay (April 30, 2013). Available at SSRN:<http://ssrn.com/abstract=2258603> or <http://dx.doi.org/10.2139/ssrn.2258603>
4. Daar, Judith F., A Clash at the Bedside: Patient Autonomy v. A Physician's Professional Conscience (June 10, 1993). Hastings Law Journal, Vol. 44, pp. 1241-1289, 1992-1993. Available at SSRN:<http://ssrn.com/abstract=1417677>
5. Ruger, Jennifer Prah, Toward a Theory of a Right to Health: Capability and Incompletely Theorized Agreements (2006). Yale Journal of Law & the Humanities, Vol. 18, pp. 273-326, 2006. Available at SSRN:<http://ssrn.com/abstract=933009>

Additional literature

1. B., Sreya, Consumer Rights and Medical Negligence (May 8, 2013). Available at SSRN:<http://ssrn.com/abstract=2290846> or <http://dx.doi.org/10.2139/ssrn.2290846>
2. Bowman, Matthew S. and Schandavel, Christopher P., The Harmony Between Professional Conscience Rights and Patients' Right of Access (February 2, 2012). Available at SSRN: <http://ssrn.com/abstract=1998363> or <http://dx.doi.org/10.2139/ssrn.1998363>
3. Bowser, Rene, Medical Civil Rights: The Exclusion of Physicians of Color from Managed Care - Business or Bias? (September 2005). U of St. Thomas Legal Studies Research Paper No. 05-14. Available at SSRN:<http://ssrn.com/abstract=834284> or <http://dx.doi.org/10.2139/ssrn.834284>
4. Chandler, Jennifer A., Does a Patient Have a Constitutional Right to the Freedom of Medical Research? Regenerative Medicine and Therapeutic Cloning Research in Canada (June 29, 2012). McGill Journal of Law & Health, Vol. 6, No. 2, 2012. Available at SSRN: <http://ssrn.com/abstract=2096344>
5. Chima, Sylvester C., Global Medicine: Is it Ethical or Morally Justifiable for Doctors and Other Healthcare Workers to Go on Strike? (December 19, 2013). 3rd Ethics, Human Rights and Medical Law Conference, Africa Health Congress 2013 Johannesburg, South Africa. 7-9 May 2013; Chima BMC Medical Ethics 2013, 14(Suppl 1):S5 doi:10.1186/1472-6939-14-S1-S5. Available at SSRN: <http://ssrn.com/abstract=2400438>

Topic 6. Legal status of medico-legal relations' participants

Objective: to learn a general concept of legal status of a patient and medical professional; to study key professional rights and responsibilities of a physician in charge as well of other participants of medico-legal relations.

Student shall know:

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

Student should be able to:

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

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' participants.
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 3 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 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?

Recommended literature

Basic literature

6. Byrne I., Ezer T. Cohen J. Overall. J, Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. – Lviv. LOBF Publisher's "Medicine and Law, 2012 – 497 pages.
7. Health and Human Rights: A Resource Guide. Available at: <http://fxb.harvard.edu/health-and-human-rights-resource-guide/>
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6. B., Sreya, Consumer Rights and Medical Negligence (May 8, 2013). Available at SSRN:<http://ssrn.com/abstract=2290846> or <http://dx.doi.org/10.2139/ssrn.2290846>
7. Bowman, Matthew S. and Schandavel, Christopher P., The Harmony Between Professional Conscience Rights and Patients' Right of Access (February 2, 2012). Available at SSRN: <http://ssrn.com/abstract=1998363> or <http://dx.doi.org/10.2139/ssrn.1998363>
8. Bowser, Rene, Medical Civil Rights: The Exclusion of Physicians of Color from Managed Care - Business or Bias? (September 2005). U of St. Thomas Legal Studies Research Paper No. 05-14. Available at SSRN:<http://ssrn.com/abstract=834284> or <http://dx.doi.org/10.2139/ssrn.834284>
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Topic 7. Defects of medical care. Medical examination and control over the quality of medical care under the legislation of Ukraine

Objective: to study the means of legal evaluation of defects of medical care; to learn legal issues of medical care quality monitoring.

Student shall know:

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

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

Recommended literature**Basic literature**

1. Byrne I., Ezer T. Cohen J. Overall. J, Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. – Lviv. LOBF Publisher's "Medicine and Law, 2012 – 497 pages.
2. Health and Human Rights: A Resource Guide. Available at: <http://fxb.harvard.edu/health-and-human-rights-resource-guide/>
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4. Klick, Jonathan and Stratmann, Thomas, Medical Malpractice Reform and Physicians in High-Risk Specialties (January 28, 2010). Journal of Legal Studies, Vol. 36, p. S121, 2007. Available at SSRN:<http://ssrn.com/abstract=870492> or <http://dx.doi.org/10.2139/ssrn.453481>
5. Shrivastava, Saurabh and Shrivastava, Prateek and Ramasamy, Jegadeesh, Exploring the Dimensions of Doctor-Patient Relationship in Clinical Practice in Hospital Settings (May 14, 2014). IJHPM International Journal of Health Policy & Management 2014; 2: 159-160, DOI: 10.15171/ijhpm.2014.40. Available at SSRN: <http://ssrn.com/abstract=2437078>

6. Dickens, Bernard, Medical Errors: Legal and Ethical Responses. International Journal of Gynecology and Obstetrics, Vol. 81, pp. 109-114, 2003. Available at SSRN: <http://ssrn.com/abstract=945681>

Additional literature

1. Luntz, Harold, Loss of Chance in Medical Negligence (January 19, 2011). U of Melbourne Legal Studies Research Paper No. 522. Available at SSRN: <http://ssrn.com/abstract=1743862> or <http://dx.doi.org/10.2139/ssrn.1743862>
2. Wolf, Susan M., Quality Assessment of Ethics in Health Care: The Accountability Revolution (1994). American Journal of Law & Medicine, Vol. 20, pp. 105-128, 1994. Available at SSRN: <http://ssrn.com/abstract=1743749>
3. Arlen, Jennifer and MacLeod, W. Bentley, Torts, Expertise and Authority: Liability of Physicians and Managed Care Organizations. Rand Journal of Economics, Vol. 36, p. 494, 2005; USC CLEO Research Paper No. C03-13; NYU Law and Economics Research Paper No. 03-06; NYU Law School, Public Law Research Paper No. 61. Available at SSRN: <http://ssrn.com/abstract=405740>
4. Tiwari, Daya Shankar, Medical Negligence in India: A Critical Study (November 4, 2013). Available at SSRN: <http://ssrn.com/abstract=2354282> or <http://dx.doi.org/10.2139/ssrn.2354282>
5. Bogdanoski, Tony, Medical Negligence Dispute Resolution: A Role for Facilitative Mediation and Principled Negotiation? (2009). Australasian Dispute Resolution Journal, Vol. 20, No. 2, pp. 77-87, 2009. Available at SSRN: <http://ssrn.com/abstract=1438472>
6. Cortez, Nathan, A Medical Malpractice Model for Developing Countries? (June 12, 2011). Drexel Law Review, Vol. 4, p. 217, 2011; SMU Dedman School of Law Legal Studies Research Paper No. 91. Available at SSRN: <http://ssrn.com/abstract=2010576>
7. Goodwin, Michele and Richardson, L. Song, Patient Negligence (2009). Law and Contemporary Problems, Vol. 72, p. 223, 2009; Minnesota Legal Studies Research Paper No. 10-53. Available at SSRN: <http://ssrn.com/abstract=1669764>
8. Baicker, Katherine and Chandra, Amitabh, Defensive Medicine and Disappearing Doctors?. Regulation, Vol. 28, No. 3, pp. 24-31, Fall 2005. Available at SSRN: <http://ssrn.com/abstract=820325>

Topic 8. Legal liability in the field of health care.

Objective: to study the issues of legal liability in the field of health care as well as algorithms and mechanisms of human rights protection therein.

Student shall know:

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

Student should be able to:

- Analyze current laws in the field of health care;
- Prepare drafts of necessary legal documents;
- Provide 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 field of health care. Grounds for release from criminal liability.
7. Compensation of moral damages for non-providing medical care or improper provision thereof: theoretical and practical means of protection.

Self-control questions

1. Provide a definition of the notion “medical mistake”.
2. Describe a procedure of mediation in the field 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?

Recommended literature

Basic literature

1. Byrne I., Ezer T. Cohen J. Overall. J, Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. – Lviv. LOBF Publisher’s “Medicine and Law, 2012 – 497 pages.
2. Health and Human Rights: A Resource Guide. Available at: <http://fxb.harvard.edu/health-and-human-rights-resource-guide/>
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Additional literature

1. Luntz, Harold, Loss of Chance in Medical Negligence (January 19, 2011). U of Melbourne Legal Studies Research Paper No. 522. Available at SSRN: <http://ssrn.com/abstract=1743862> or <http://dx.doi.org/10.2139/ssrn.1743862>
2. Wolf, Susan M., Quality Assessment of Ethics in Health Care: The Accountability Revolution (1994). American Journal of Law & Medicine, Vol. 20, pp. 105-128, 1994. Available at SSRN: <http://ssrn.com/abstract=1743749>
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Content module 3. Legal regulation of certain types of medical activity

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

Objective: to learn international and regional standards, and national laws, which regulate the issues of dental care provision; to analyze and learn the defects of dental care provision, peculiarities of carrying out dental practice.

Student shall know:

- List of key legal acts on the topic;
- International and regional standards;
- Legal status of a dentist;
- Peculiarities of carrying out dental practice;
- Procedure of preparing medical records.

Student should be able to:

- Analyze relevant laws in the field of health care;
- Characterize international and regional standards in the field of health care;
- Prepare an algorithm of actions for persons, who are going to carry out dental practice.

Plan of the class

1. General characteristics of the legislation, which regulates dental practice in Ukraine.
2. The notion and types of dental care.
3. The notion and types of defects of dental care. Legal qualification of defects of dental care.
4. Legal regulation of prophylactics of dental diseases.
5. Peculiarities of carrying out dental practice.

Self-control questions

1. Provide examples of legal acts, which are dedicated to legal regulation of dental care.
2. Enumerate several examples of legal acts, which regulate dental care provision in your country.
3. Give the definition of the notion “dental care”.
4. Enumerate different types of dental care.
5. What requirements shall a dentist meet?
6. What rights does dentist have?
7. What responsibility does dentist have?
8. What patient’s rights in the field of dentistry do you know?
9. Enumerate 3 examples of patient’s rights violations in the field of dentistry.

10. Describe conditions for carrying out dental practice in your country.

Recommended literature

Basic literature

1. Byrne I., Ezer T. Cohen J. Overall. J, Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. – Lviv. LOBF Publisher’s “Medicine and Law, 2012 – 497 pages.
2. Health and Human Rights: A Resource Guide. Available at: <http://fxb.harvard.edu/health-and-human-rights-resource-guide/>
3. Shrivastava, Saurabh and Shrivastava, Prateek and Ramasamy, Jegadeesh, Exploring the Dimensions of Doctor-Patient Relationship in Clinical Practice in Hospital Settings (May 14, 2014). IJHPM International Journal of Health Policy & Management 2014; 2: 159-160, DOI: 10.15171/ijhpm.2014.40. Available at SSRN: <http://ssrn.com/abstract=2437078>
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5. Wei, Marlynn, Doctors, Apologies, and the Law: An Analysis and Critique of Apology Laws. Journal of Health Law, Vol. 39, No. 4, Fall 2006. Available at SSRN: <http://ssrn.com/abstract=955668>
6. Peeples, Ralph A. and Harris, Catherine T. and Metzloff, Thomas B., The Process of Managing Medical Malpractice Cases: The Role of Standard of Care. Wake Forest Law Review, Vol. 37, p. 877. Available at SSRN:<http://ssrn.com/abstract=347760> or <http://dx.doi.org/10.2139/ssrn.347760>

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1. Luntz, Harold, Loss of Chance in Medical Negligence (January 19, 2011). U of Melbourne Legal Studies Research Paper No. 522. Available at SSRN: <http://ssrn.com/abstract=1743862> or <http://dx.doi.org/10.2139/ssrn.1743862>
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8. Wolf, Susan M., Conflict Between Doctor and Patient (Winter 1988). Law, Medicine & Health Care, Vol. 16, pp. 197-203, 1988. Available at SSRN: <http://ssrn.com/abstract=1739984>

Topic 10. Legal regulation of family medicine in Ukraine.

Objective: to study basic legal aspects of family medicine, legal status of a family doctor; to clarify legal basics of healing (traditional medicine).

Student shall know:

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

Student should be able to:

- Analyze current laws in the field of family medicine and healing;
- Prepare drafts of necessary legal documents;
- Research the role and importance of family medicine taking into account 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 family medicine in your country.

Self-control questions

1. Characterize the notion “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, if any.
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 issues of family medicine development in Ukraine and in your country.
9. Characterize legal basics of family medicine organization.
10. Characterize the system of family medicine in your country.

Recommended literature

Basic literature

1. Byrne I., Ezer T. Cohen J. Overall. J, Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. – Lviv. LOBF Publisher’s “Medicine and Law, 2012 – 497 pages.
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4. Daar, Judith F., A Clash at the Bedside: Patient Autonomy v. A Physician's Professional Conscience (June 10, 1993). *Hastings Law Journal*, Vol. 44, pp. 1241-1289, 1992-1993. Available at SSRN:<http://ssrn.com/abstract=1417677>

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2. Bowman, Matthew S. and Schandavel, Christopher P., The Harmony Between Professional Conscience Rights and Patients' Right of Access (February 2, 2012). Available at SSRN: <http://ssrn.com/abstract=1998363> or <http://dx.doi.org/10.2139/ssrn.1998363>

3. Bowser, Rene, Medical Civil Rights: The Exclusion of Physicians of Color from Managed Care - Business or Bias? (September 2005). U of St. Thomas Legal Studies Research Paper No. 05-14. Available at SSRN:<http://ssrn.com/abstract=834284> or <http://dx.doi.org/10.2139/ssrn.834284>

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

Objective: to study international and regional standards, and national laws, which regulate the issues of prophylactics and treatment of infectious diseases; to analyze the aspects of sanitary and epidemiological protection in Ukraine.

Student shall 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.

Student should be able to:

- Analyze current laws in the field of health care;
- Characterize international and regional standards in the field 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' participants 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 field 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 deal 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 field 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 deals 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.

Recommended literature

Basic literature

1. Byrne I., Ezer T. Cohen J. Overall. J, Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. – Lviv. LOBF Publisher's "Medicine and Law, 2012 – 497 pages.
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Topic 12. Legal regulation of donation in Ukraine

Objective: to form of basic knowledge as regards to reproductive health of the population and reproductive technologies; to study legal basics of donation in Ukraine.

Student shall know:

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

Student should be able to:

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

Plan of the class

1. Notion and types of donation under the laws of Ukraine.
2. Legal regulation of blood and its components donation.
3. Legal regulation of organ and other anatomic materials donation.
4. Describe the essence of presumption of consent for donation.
5. What is a waiting list in the field of donation?
6. Characterize the issue of organ transplantation from a dead person.
7. Is it allowed to transplant organs from a dead person in your country?
8. Characterize the system of organ donation in your country.
9. Is donation for commercial purposes allowed? Explain your opinion.
10. Who can be a donor of an organ?

Self-control questions

1. Define the notion “assisted reproductive technologies”.
2. Enumerate human rights in the field of assisted reproductive technologies application.
3. Describe human right to 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 field of surrogate motherhood.
9. Define a legal status of a surrogate mother.
10. Characterize legal aspects of sex reassignment in your country.

Recommended literature

Basic literature

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

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

Student shall 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.

Student should be able to:

- Analyze relevant laws in the field 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 pharmaceutical activity 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 offences.

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 of medicines sales?
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.

Recommended literature

Basic literature

1. Byrne I., Ezer T. Cohen J. Overall. J, Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. – Lviv. LOBF Publisher’s “Medicine and Law, 2012 – 497 pages.
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Additional literature

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

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

Student shall know:

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

Student should be able to:

- Analyze relevant laws in the field 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 exercising;
- Explain the mechanisms of exercising 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 field of tobacco fighting.
3. Peculiarities of children's rights exercising in Ukraine.
4. Legal regulation of psychiatric care provision.

5. Legal status of medical professionals, who deal with mentally ill patients.
6. Legal regulation of providing medical care to marginalized groups.

Self-control questions

1. Give a definition of the notion “person with disability”.
2. Describe the grounds for declaring a patient of 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’s rights exercising in the field of health care.
7. Explain the state policy of your state in the field of tobacco fighting.
8. Enumerate at least 6 rights of children in the field 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.

Recommended literature

Basic literature

1. Byrne I., Ezer T. Cohen J. Overall. J, Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. – Lviv. LOBF Publisher’s “Medicine and Law, 2012 – 497 pages.
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Emanuel, ed., Harvard University Press, 1998. Available at SSRN:<http://ssrn.com/abstract=1743102>

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

Objective: to study international and regional standards, and national laws, which regulate palliative care; to learn the peculiarities of hospices functioning and mechanisms of palliative care provision; to clarify legal status of doctor and patient as well as other participants in the course of palliative care provision.

Student shall know:

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

Student should be able to:

- Analyze relevant laws in the field of health care;
- Characterize international and regional standards in the field of health care;
- Explain legal status of a physician, who provides 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' participants in the course of palliative care provision.
5. Legal status of a hospice.

Self-control questions

1. Provide a definition of the notion "hospice".
2. Provide a definition of the notion "palliative care".
3. Enumerate the main components of palliative care.
4. Describe legal grounds for palliative care provision.
5. Enumerate patient rights in the field of palliative care.
6. Describe legal status of a medical professional, who provides palliative care.
7. What does the right of patient to respect of dignity mean?
8. Enumerate at least 4 examples of human rights violations in the field of palliative care.
9. What international standards regulate the issues of palliative care provision?
10. Characterize the system of palliative care in your country.

Recommended literature

Basic literature

1. Byrne I., Ezer T. Cohen J. Overall. J, Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. – Lviv. LOBF Publisher’s “Medicine and Law, 2012 – 497 pages.
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5. Smith, George P., Strategizing the End-Game: Palliative Medicine and the Law (March 7, 2012). CUA Columbus School of Law Legal Studies Research Paper No. 2012-4. Available at SSRN: <http://ssrn.com/abstract=2027533>
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6. Johnson, Sandra H., Make Room for Dying: End of Life Care in Nursing Homes (2005). Hastings Center Report, Vol. 35, No. 6, p. S37, November-December, 2005; Saint Louis U. Legal Studies Research Paper . Available at SSRN: <http://ssrn.com/abstract=1682115>

LIST OF QUESTIONS FOR STUDENTS, WHO PREPARE FOR THE DISCIPLINE

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

30. Formation and development of new technologies in the field of health care (including telemedicine, cybermedicine, quantum medicine).
31. General provisions on healthcare insurance: concepts, principles of insurance, subject matter, participants, objects and composition of the insurance relationships.
32. Voluntary medical insurance: current status of legal regulation and application.
33. Formation and development of compulsory state social health insurance.
34. Professional insurance of medical professionals' liability.
35. Insurance of medical and pharmaceutical professionals, who perform their professional duties in specific areas of medical practice.
36. The concept and features of medical care (high-quality, qualified and free of charge medical care).
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