

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



[Handwritten signature]

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: 222 “Medicine”

<p>Discussed and adopted on the meeting of the Department <u>30, April</u> 2021 Minutes No. <u>9</u> of <u>30.04.2021</u> Head of the Department, professor I. Y. Senyuta <i>[Handwritten signature]</i> signature</p>	<p>Approved By the profile methodic commission <u>20</u> <u>May</u> 2021 Minutes No. <u>2</u> of <u>20.05.2021</u> Head of the commission, dean of the FPGE, associate professor <u>O. Y. Sichkoriz</u> <i>[Handwritten signature]</i> signature</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

2021

[Handwritten signature]

Self-reliant work of students and its control

	Topic	S RW	Type of control
	Content module 1. Medical Law as a Legal Phenomenon	6	
	Medical law in the system of law and system of legislation	1	Current control during practical classes
	Legal regulation of health care system in Ukraine	1	
	International standards in the field of health care and human rights	2	
	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	6	
	Legal status of medico-legal relations' participants	1	Current control during practical classes
	The system of human rights in patient care. Personal non-proprietary rights	1	
	Defects of medical care. Medical examination and control over the quality of medical care under the legislation of Ukraine	2	
	Legal liability in the field of health care. Procedures and mechanism for the medico-legal relations' participants rights protection.	2	
	Content module 3. Legal Regulation of Certain Types of Medical Activity	13	
	Legal regulation of family medicine in Ukraine. Traditional medicine (healing) under the laws of Ukraine.	1	Current control during practical classes
	Legal regulation of prophylactics and treatment of infectious diseases. Legal regulation of sanitary and epidemiological welfare in Ukraine	2	
	Donation under the laws of Ukraine. Legal regulation of reproductive health and reproductive technologies in Ukraine. Gender adjustment	2	
	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	
	Legal regulation of psychiatric care. Legal regulation of providing medical care to the vulnerable groups of the population	2	
	Legal regulation of palliative care. Legal organization of hospices functioning in Ukraine	2	
	Legal regulation of cosmetology and sports, and fitness activity (sports medicine). Sanatorium and spa activity. Medical tourism.	2	
	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](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](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. 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**

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. 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

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/>
8. 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>
9. 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>
10. 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

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>
9. 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>
10. 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 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/>
3. Jackman, Martha, Misdiagnosis or Cure? Charter Review of the Health Care System (2006). in C.M. Flood, ed., Just Medicare: What's In, What's Out, How We Decide (Toronto: University of Toronto Press, 2006) 58-79.. Available at SSRN: <http://ssrn.com/abstract=2304511>
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. Procedures and mechanism for the medico-legal relations' participants rights protection.

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/>
3. Jackman, Martha, Misdiagnosis or Cure? Charter Review of the Health Care System (2006). in C.M. Flood, ed., Just Medicare: What’s In, What’s Out, How We Decide (Toronto: University of Toronto Press, 2006) 58-79.. Available at SSRN: <http://ssrn.com/abstract=2304511>
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>

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>

Content module 3. Legal regulation of certain types of medical activity

Topic 9. Legal regulation of family medicine in Ukraine. Traditional medicine (healing) under the laws of 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.
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. Vafae-Najar, Ali and Nejtzadegan, Zohreh and Pourtaleb, Arefeh and Kaffashi, Shahnaz and Vejdani, Marjan and Molavi-Taleghani, Yasamin and Ebrahimipour, Hosein, The Quality Assessment of Family Physician Service in Rural Regions, Northeast of Iran in 2012 (April 10, 2014). Int J Health Policy Manag 2014; 2: 137–142. doi: 10.15171/ijhpm.2014.35. Available at SSRN: <http://ssrn.com/abstract=2424487>

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. Jamouille, Marc, Quaternary Prevention, An Answer of Family Doctors to Overmedicalization (February 8, 2015). Int J Health Policy Manag 2015; 4: 61–64. doi: 10.15171/ijhpm.2015.24. Available at SSRN:<http://ssrn.com/abstract=2561977>
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 10. 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.
2. Health and Human Rights: A Resource Guide. Available at: <http://fxb.harvard.edu/health-and-human-rights-resource-guide/>
3. Sinha, Tapen and Condon, Bradly J., AIDS Prevention, Treatment and Legal Rights: Local Strategies for a Global Disease (April 2006). Available at SSRN: <http://ssrn.com/abstract=896962> or <http://dx.doi.org/10.2139/ssrn.896962>
4. Burris, Scott and Gostin, Lawrence O., The Impact of HIV/AIDS on the Development of Public Health Law. Dawning answers: how the HIV/AIDS epidemic has helped to

strengthen public health, Ronald O. Valdiserri, ed., pp. 96-117, Oxford University Press, 2003. Available at SSRN:<http://ssrn.com/abstract=1022029>

5. Gable, Lance and Gostin, Lawrence O. and Hodge, James G., A Global Assessment of the Role of Law in the HIV/AIDS Pandemic (May 18, 2009). Public Health, Vol. 123, pp. 260-264, 2009; Wayne State University Law School Research Paper No. 10-25. Available at SSRN: <http://ssrn.com/abstract=1406573> or <http://dx.doi.org/10.2139/ssrn.1406573>

6. Jacobi, John, Prison Health, Public Health: Obligations and Opportunities (August 18, 2005). Seton Hall Public Law Research Paper No. 43. Available at SSRN: <http://ssrn.com/abstract=789007> or <http://dx.doi.org/10.2139/ssrn.789007>

7. Gostin, Lawrence O. and Burris, Scott and Lazzarini, Zita, The Law and the Public's Health: A Study of Infectious Disease Law in the United States. Columbia Law Review, January 1999. Available at SSRN:<http://ssrn.com/abstract=139923>

8. Thorogood, Adrian and Zawati, Ma'n H. and Knoppers, Bartha M, Point-of-Care Genetic Tests for Infectious Disease: Legal Considerations (2014). Current Pharmacogenomics and Personalized Medicine, 2014, 12, 43-50. Available at SSRN: <http://ssrn.com/abstract=2643789>

Additional literature

1. Maske, Niharika and Khare, Shubham Manoj, HIV/Aids and Human Rights: An Indian Perspective (August 22, 2009). Available at SSRN: <http://ssrn.com/abstract=1459604> or <http://dx.doi.org/10.2139/ssrn.1459604>

2. Schuklenk, Udo and Philpott, Sean, AIDS: The Time for Changes in Law and Policy is Now (March 26, 2011). International Journal of Law in Context, Forthcoming. Available at SSRN: <http://ssrn.com/abstract=1796032>

3. Meier, Benjamin Mason and Brugh, Kristen Nichole and Halima, Yasmin, Conceptualizing a Human Right to Prevention in Global HIV/AIDS Policy (October 2, 2012). Public Health Ethics, (online), Forthcoming; UNC Legal Studies Research Paper No. 2155933. Available at SSRN: <http://ssrn.com/abstract=2155933>

4. Rothstein, Mark A., From SARS to Ebola: Legal and Ethical Considerations for Modern Quarantine (January 9, 2015). Indiana Health Law Review, vol.12, no.1, 2015 Forthcoming; University of Louisville School of Law Legal Studies Research Paper Series No. 2015-03. Available at SSRN: <http://ssrn.com/abstract=2499701> or <http://dx.doi.org/10.2139/ssrn.2499701>

Topic 11. Donation under the laws of Ukraine. Legal regulation of reproductive health and reproductive technologies in Ukraine. Gender adjustment

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. 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 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

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. Fevrier, Philippe and Gay, Sebastien, Informed Consent Versus Presumed Consent: The Role of the Family in Organ Donations (June 2004). Available at SSRN: <http://ssrn.com/abstract=572241> or <http://dx.doi.org/10.2139/ssrn.572241>
4. Martyn, Susan R. and Wright, Richard and Clarke, Leo L., Required Request for Organ Donation: Moral, Clinical and Legal Problems (1988). Required Request Revisited, Hastings Center Report, Vol. 19, No. 44, March/April 1989; Required Request Revisited, Hastings Center Report, Vol. 19, No. 44, March/April 1989. Available at SSRN: <http://ssrn.com/abstract=1160001>
5. Goodwin, Michele, Empires of the Flesh: Organ and Tissue Taboos (2009). Alabama Law Review, Vol. 60, No. 5, p. 1219, 2009; Minnesota Legal Studies Research Paper No. 10-49. Available at SSRN: <http://ssrn.com/abstract=1669739>
6. August, Jonathan, Modern Models of Organ Donation: Challenging Increases of Federal Power to Save Lives (January 9, 2013). Hastings Constitutional Law Quarterly, Vol. 40, No. 2, 2013. Available at SSRN: <http://ssrn.com/abstract=2228968>
7. Harrington, Maxine M, The Thin Flat Line: Redefining Who Is Legally Dead in Organ Donation After Cardiac Death (February 17, 2009). Denver University Law Review, Vol. 86, No. 2, 2009. Available at SSRN: <http://ssrn.com/abstract=1345469>
8. Bonnie, Richard J. and Siegal, Gil, Closing the Organ Gap: A Reciprocity-Based Social Contract Approach (2006). Journal of Law, Medicine and Ethics, 2006. Available at SSRN: <http://ssrn.com/abstract=1759984>

9. Fitzpatrick, Thomas I. and Fry-Revere, Sigrid and Zhu, Huan, Legal Trends in Bioethics (August 13, 2013). Legal Trends in Bioethics Online Issue, No. 6, Summer-Fall 2013. Available at SSRN:<http://ssrn.com/abstract=2309491>
10. Dickens, Bernard and Cook, Rebecca J., Ethical and Legal Issues in Assisted Reproductive Technology. International Journal of Gynecology and Obstetrics, Vol. 66, pp. 55-61, 1999. Available at SSRN:<http://ssrn.com/abstract=946490>
11. Kindregan, Jr., Charles P., Thinking About the Law of Assisted Reproductive Technology. Wisconsin Journal of Family Law, Vol. 27, p. 123, 2007; Suffolk University Law School Research Paper No. 08-01. Available at SSRN:<http://ssrn.com/abstract=1067043>
12. Cohen, I. Glenn, The Right Not to Be a Genetic Parent? (2008). Southern California Law Review, Vol. 81, p. 1115, 2008; Harvard Public Law Working Paper No. 08-31. Available at SSRN:<http://ssrn.com/abstract=1116269>
13. Todres, Jonathan, The Importance of Realizing 'Other Rights' to Prevent Sex Trafficking. Cardozo Journal of Law and Gender, Vol. 12, pp. 885-907, 2006; NYU Law School, Public Law Research Paper No. 06-17. Available at SSRN: <http://ssrn.com/abstract=912250>

Additional literature

1. Orentlicher, David, Presumed Consent to Organ Donation: Its Rise and Fall in the United States (August 6, 2008). Rutgers Law Review, Vol. 61, p. 295, 2009. Available at SSRN: <http://ssrn.com/abstract=1207862>
2. Articulo, Archimedes Carag, Organs, Money, & Dignity: Immanuel Kant on the Incentive Question in Living Organ Donation (November 9, 2009). Available at SSRN: <http://ssrn.com/abstract=1502623> or <http://dx.doi.org/10.2139/ssrn.1502623>
3. Beard, Thomas Randolph and Jackson, John D. and Kaserman, David L., The Failure of U.S. Organ Procurement Policy. Regulation, Vol. 30, No. 4, Winter 2007-2008. Available at SSRN:<http://ssrn.com/abstract=1092920>
4. Raj, Madhusudan, Blood Donation and/or Blood Trade (September 5, 2011). Available at SSRN:<http://ssrn.com/abstract=1922931> or <http://dx.doi.org/10.2139/ssrn.1922931>
5. Mocan, Naci H. and Tekin, Erdal, The Determinants of the Willingness to Be an Organ Donor (May 2005). NBER Working Paper No. w11316. Available at SSRN: <http://ssrn.com/abstract=721103>
6. Storrow, Richard F., Quests for Conception: Fertility Tourists, Globalization and Feminist Legal Theory. Hastings Law Journal, Vol. 57, p. 295, 2006. Available at SSRN: <http://ssrn.com/abstract=879072>
7. Cook, Rebecca J. and Erdman, Joanna N. and Dickens, Bernard, Respecting Adolescents' Confidentiality and Reproductive and Sexual Choices. International Journal of Gynecology and Obstetrics, Vol. 98, pp. 182-187, 2007; U Toronto, Legal Studies Research Paper No. 08-08. Available at SSRN:<http://ssrn.com/abstract=1010442>
8. Cook, Rebecca J. and Dickens, Bernard, From Reproductive Choice to Reproductive Justice (2009). International Journal of Gynecology and Obstetrics, Vol. 106, pp. 106-109, 2009. Available at SSRN:<http://ssrn.com/abstract=1437637>

Topic 12. 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.
2. Health and Human Rights: A Resource Guide. Available at: <http://fxb.harvard.edu/health-and-human-rights-resource-guide/>
3. Roin, Benjamin N., Unpatentable Drugs and the Standards of Patentability (February 2009). Texas Law Review, Vol. 87, pp. 503-570, 2009. Available at SSRN: <http://ssrn.com/abstract=1127742>
4. Volokh, Eugene, Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs. Harvard Law Review, Vol. 120, April 2007; University of California, Los Angeles - School of Law Research Paper No. 06-42. Available at SSRN: <http://ssrn.com/abstract=941868>

5. Rubin, Paul H., Pharmaceutical Marketing: Medical and Industry Biases. *Journal of Pharmaceutical Finance, Economics & Policy*, Forthcoming. Available at SSRN: <http://ssrn.com/abstract=488263>
6. Rubin, Paul H., Medical Research on Pharmaceutical Marketing: Is a Bias Ever Just a Bias?. Available at SSRN: <http://ssrn.com/abstract=434861> or <http://dx.doi.org/10.2139/ssrn.434861>
7. Lemmens, Trudo and Telfer, Candice, Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency (September 22, 2011). *American Journal of Law and Medicine*, Vol. 38, pp. 63-112, 2012. Available at SSRN: <http://ssrn.com/abstract=1932436>
8. Rodwin, Marc A., Reforming Pharmaceutical Industry-Physician Financial Relationships: Lessons from the United States, France, and Japan (2011). *Journal of Law, Medicine and Ethics*, Vol. 39, p. 662, 2011; Suffolk University Law School Research Paper No. 11-36. Available at SSRN: <http://ssrn.com/abstract=1926361>

Additional literature

1. Schipper, Irene and Weyzig, Francis, Ethics for Drug Testing in Low and Middle Income Countries: Considerations for European Market Authorisation (February 17, 2008). Stichting Onderzoek Multinationale Ondernemingen, February 2008. Available at SSRN: <http://ssrn.com/abstract=1660433>
2. Van Overwalle, Geertrui, Clinical Trials - The Situation in Belgium in the Light of Recent Case Law in the Netherlands and Germany (Proeven met geneesmiddelen - De situatie in België in het licht van de recente rechtspraak en rechtsleer in Nederland en Duitsland) (December 1, 2010). *PATENT LAW AND MEDICINES*, pp. 65-91, G. Van Overwalle, ed., Brussel, Bruylant, 2000. Available at SSRN: <http://ssrn.com/abstract=1718624>
3. Holman, Christopher M., Unpredictability in Patent Law and Its Effect on Pharmaceutical Innovation (2011). *Missouri Law Review*, Vol. 76, p. 645, 2011. Available at SSRN: <http://ssrn.com/abstract=2581168>
4. Cave, Emma, Seen But Not Heard: Children in Clinical Trials. (2010) 18(1) *Medical Law Review*, 1-27. Available at SSRN: <http://ssrn.com/abstract=2503353>
5. Berndt, Ernst R. and Cockburn, Iain M. and Thiers, Fabio A., The Globalization of Clinical Trials for New Medicines: Where are the Trials Going and Why? (June 2007). *iHEA 2007 6th World Congress: Explorations in Health Economics Paper*. Available at SSRN: <http://ssrn.com/abstract=992483>
6. Taneja, Girish, Influence of Promotional Tools Offered by Pharmaceutical Industry on Physicians Prescribing Behavior (December 1, 2007). Available at SSRN: <http://ssrn.com/abstract=2049747> or <http://dx.doi.org/10.2139/ssrn.2049747>

Topic 13. 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.
2. Health and Human Rights: A Resource Guide. Available at: <http://fxb.harvard.edu/health-and-human-rights-resource-guide/>
3. Radden, Jennifer, Psychiatric Ethics. Bioethics, Vol. 16, pp. 397-411, 2002. Available at SSRN: <http://ssrn.com/abstract=324645>
4. Gostin, Lawrence O. and Gable, Lance, The Human Rights of Persons with Mental Disabilities: A Global Perspective on the Application of Human Rights Principles to Mental Health (May 19, 2009). Maryland Law Review, Vol. 63, No. 20, 2004; Wayne State University Law School Research Paper No. 08-31. Available at SSRN: <http://ssrn.com/abstract=1435443>
5. Perlin, Michael L. and Szeli, Eva, Mental Health Law and Human Rights: Evolution and Contemporary Challenges. NYLS Legal Studies Research Paper No. 07/08-28; NYLS Legal Studies Research Paper No. 07/08-28. Available at SSRN: <http://ssrn.com/abstract=1132428>
6. Gable, Lance and Gostin, Lawrence O., Mental Health as a Human Right (June 18, 2009). SWISS HUMAN RIGHTS BOOK, Vol. 3, pp. 249-261, Rüffer & Rub, 2009; Wayne State

University Law School Research Paper No. 09-15. Available at SSRN: <http://ssrn.com/abstract=1421901> or <http://dx.doi.org/10.2139/ssrn.1421901>

7. Bennion, Elizabeth, A Right to Remain Psychotic? A New Standard for Involuntary Treatment in Light of Current Science (May 3, 2013). Loyola of Los Angeles Law Review, Forthcoming. Available at SSRN: <http://ssrn.com/abstract=2260469>

8. Petrila, John and Swanson, Jeffrey W., Mental Illness, Law, and a Public Health Law Research Agenda (December 6, 2010). Available at SSRN: <http://ssrn.com/abstract=1721189> or <http://dx.doi.org/10.2139/ssrn.1721189>

Additional literature

1. Johnston, E. Lea, Theorizing Mental Health Courts (April 15, 2011). Washington University Law Review, Vol. 89; University of Florida Levin College of Law Research Paper No. 2010-21. Available at SSRN: <http://ssrn.com/abstract=1710882> or <http://dx.doi.org/10.2139/ssrn.1710882>

2. Wolf, Susan M., Facing Assisted Suicide and Euthanasia in Children and Adolescents (1998). REGULATING HOW WE DIE: THE ETHICAL, MEDICAL, AND LEGAL ISSUES SURROUNDING PHYSICIAN-ASSISTED SUICIDE, pp. 92-119, 274-294, Linda L. Emanuel, ed., Harvard University Press, 1998. Available at SSRN: <http://ssrn.com/abstract=1743102>

3. Alemanno, Alberto, Out of Sight Out of Mind - Towards a New EU Tobacco Products Directive (January 24, 2012). Columbia Journal of European Law, Vol. 18, No. 2, Spring 2012. Available at SSRN: <http://ssrn.com/abstract=1991289>

4. Gostin, Lawrence O. and Sridhar, Devi, Global Health and the Law (May 1, 2014). The New England Journal of Medicine, Vol. 370, pp. 1732-1740, 2014. Available at SSRN: <http://ssrn.com/abstract=2439625>

Topic 14. 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.
2. Health and Human Rights: A Resource Guide. Available at: <http://fxb.harvard.edu/health-and-human-rights-resource-guide/>
3. Radden, Jennifer, Psychiatric Ethics. Bioethics, Vol. 16, pp. 397-411, 2002. Available at SSRN:<http://ssrn.com/abstract=324645>
4. Magnusson, Roger, The Devil's Choice: Re-Thinking Law, Ethics and Symptom Relief in Palliative Care. Journal of Law, Medicine and Ethics, Vol. 34, No. 3, Fall 2006; Sydney Law School Research Paper No. 06/22. Available at SSRN: <http://ssrn.com/abstract=901560>
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>
6. Cerminara, Kathy L., Hospice and Health Care Reform: Improving Care at the End of Life (October 15, 2010). Widener Law Review, Vol. 16, 2011; NSU Shepard Broad Law Center Research Paper No. 10-012. Available at SSRN: <http://ssrn.com/abstract=1694196>
7. Orentlicher, David, The Supreme Court and Terminal Sedation: Rejecting Assisted Suicide, Embracing Euthanasia (March 24, 2012). Hastings Constitutional Law Quarterly, Vol. 24, p. 947, 1997. Available at SSRN:<http://ssrn.com/abstract=2028321>
8. Smith, George P., Managing End-of-Life Care: Medico-Legal, Social, Ethical and Philosophical Challenges (November 9, 2011). CUA Columbus School of Law Legal Studies Research Paper No. 2011-21. Available at SSRN: <http://ssrn.com/abstract=1960588>

Additional literature

1. Stern, Ruth C. and DiFonzo, J. Herbie, Stopping for Death: Re-Framing Our Perspective on the End of Life (September 18, 2009). Hofstra Univ. Legal Studies Research Paper No. 09-21. Available at SSRN:<http://ssrn.com/abstract=1475348> or <http://dx.doi.org/10.2139/ssrn.1475348>
2. Ouellette, Alicia R. and Quill, Timothy and Swidler, Robert and Pope, Thaddeus Mason and Dubler, Nancy, A Conversation About End-of-Life Decisionmaking (January 8, 2010). NYSBA Health Law Journal Vol. 14, No. 2, 2009; Widener Law School Legal Studies Research Paper No. 10-05. Available at SSRN:<http://ssrn.com/abstract=1533517>

3. Smith, George P., Refractory Pain, Existential Suffering, and Palliative Care: Releasing an Unbearable Lightness of Being (March 1, 2011). Cornell Journal of Law and Public Policy, Vol. 20, No. 3, pp. 469-532, 2011; CUA Columbus School of Law Legal Studies Research Paper No. 2011-7. Available at SSRN:<http://ssrn.com/abstract=1804326>

4. Pope, Thaddeus Mason and Anderson, Lindsey E., Voluntarily Stopping Eating and Drinking: A Legal Treatment Option at the End of Life (October 7, 2010). Widener Law Review, Vol. 17, p. 363, 2011; Widener Law School Legal Studies Research Paper No. 10-35. Available at SSRN: <http://ssrn.com/abstract=1689049>

5. Tucker, J. D., Kathryn L., Medico-Legal Case Report and Commentary: Inadequate Pain Management in the Context of Terminal Cancer - The Case of Lester Tomlinson (September, 24 2008). Pain Medicine, Vol. 5, No. 2, 2004. Available at SSRN: <http://ssrn.com/abstract=1272842>

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>

Topic 15. Legal regulation of cosmetology and sports and fitness activity (sports medicine). Sanatorium and spa activity. Medical tourism.

Objective: to study 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.

Student shall 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.

Student should be able to:

- Analyze relevant laws in the field of health care;
- Prepare necessary legal documents;
- Characterize international and regional standards in the field 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 field of sports medicine and cosmetology.
2. Describe 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 field of cosmetology and sports medicine 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/>
3. Calandrillo, Steve, Sports Medicine Conflicts: Team Physicians vs. Athlete-Patients. St. Louis University Law Journal, Fall 2005. Available at SSRN: <http://ssrn.com/abstract=755030>
4. 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>
5. Bogdanoski, Tony, Every Body is Different: Regulating the Use (and Non-Use) of Cosmetic Surgery, Body Modification and Reproductive Genetic Testing (2009). Griffith Law Review, Vol. 18, No. 2, pp. 503-528, 2009; Sydney Law School Research Paper No. 10/62. Available at SSRN: <http://ssrn.com/abstract=1505768>
6. 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>
7. 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>
8. Larcombe, Wendy, Cosmetic Surgery, Choice and Regulation (May 15, 2012). U of Melbourne Legal Studies Research Paper No. 590. Available at SSRN: <http://ssrn.com/abstract=2060709> or <http://dx.doi.org/10.2139/ssrn.2060709>
9. Verwey, Hanneke and Carstens, Pieter, Informed Consent to Cosmetic Surgery – Does a Broader Duty of Disclosure Exist? (November 29, 2013). Journal of Contemporary Roman-Dutch Law, Vol. 76, p. 642-653, 2013. Available at SSRN: <http://ssrn.com/abstract=2430623>

Additional literature

1. 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>
2. 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>
3. 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>
4. 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>
5. Jackman, Martha, Misdiagnosis or Cure? Charter Review of the Health Care System (2006). in C.M. Flood, ed., Just Medicare: What's In, What's Out, How We Decide (Toronto: University of Toronto Press, 2006) 58-79.. Available at SSRN: <http://ssrn.com/abstract=2304511>

6. 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>
7. Ramseyer, J. Mark, Talent and Expertise under Universal Health Insurance: The Case of Cosmetic Surgery in Japan (October 2007). Harvard Law School Law & Economics, Research Paper No. 600; 3rd Annual Conference on Empirical Legal Studies Papers. Available at SSRN: <http://ssrn.com/abstract=1028087>
8. Cook, Rebecca J. and Dickens, Bernard, Hymen Reconstruction: Ethical and Legal Issues (December 1, 2009). International Journal of Gynecology and Obstetrics, Vol. 107, pp. 266-269, 2009. Available at SSRN:<http://ssrn.com/abstract=1518068>

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).
37. The right to health care under the laws of Ukraine.
38. Medical service as an object of medico-legal relationship.
39. Medical services agreement: concept, general characteristics and features of fulfillment.
40. Contractual liability in the field of health care.
41. Human rights in patient care: concepts, classification, general characteristics.
42. Guarantees of human rights in patient care provision.
43. The right to life: concept, content and general characteristics. The right to life and medical practice: the issue of value.
44. The concept and structure of the human right to health care under the laws of Ukraine.
45. The right to medical information: general characteristics and legal regulation.
46. The right to medical confidentiality: general characteristics and legal support.
47. The right to consent to medical intervention.
48. The right to refuse from medical intervention.
49. The procedure of personal data processing in the field of health care.
50. Concept and types of medico-legal relations.
51. Patient: Definitional and classification approaches.
52. General characteristics of the patient.
53. Legal regulation of patient's responsibilities in Ukraine.
54. The moral and ethical principles of "doctor-patient" relations.
55. Features of the legal status of the legal representatives in the field of health care.
56. Medical professional and his/her legal status: conceptual-categorical apparatus and classification.
57. Legal regulation of rights of medical professionals.
58. Legal regulation of professional responsibilities of medical professionals.
59. Legal status of the doctor in charge under the national laws.
60. Concept and types of procedures and mechanisms for the protection of medico-legal relations participants' rights.

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

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

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. Council of Europe, Convention for the Protection of Human Rights and Fundamental Freedoms. conventions.coe.int/Treaty/en/Treaties/Html/005.htm.
7. Council of Europe, European Social Charter (1996 revised edition). conventions.coe.int/Treaty/EN/Treaties/Html/035.htm.
8. Active Citizen Network, European Charter of Patients' Rights (2002). www.eesc.europa.eu/self-and-coregulation/documents/codes/private/085-private-act.pdf
9. 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>.
10. 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>
11. European Court of Human Rights. Case of Z. v. Finland. Available at: <http://hudoc.echr.coe.int/eng?i=001-58033>
12. European Court of Human Rights. Case of V.C. v. Slovakia. Available at: <http://hudoc.echr.coe.int/eng?i=001-107364>
13. European Court of Human Rights. Case Arskaya v. Ukraine. Available at: <http://hudoc.echr.coe.int/eng?i=001-138590>
14. European Court of Human Rights. Case VO v. France. Available at: <http://hudoc.echr.coe.int/eng?i=001-61887>
15. European Court of Human Rights. Case CSOMA v. Romania. Available at: <http://hudoc.echr.coe.int/eng?i=001-115862>
16. European Court of Human Rights. Case G.B. and R.B. v. Moldova. Available at <http://hudoc.echr.coe.int/eng?i=001-115395>