

BOGOMOLETS NATIONAL MEDICAL UNIVERSITY

Department of Forensic Medicine and Medical Law

GUIDELINES to the lecture No. 2 ON TOPIC No. 4:

“Basics of economic activity and insurance in the field of health care. Legal nature of medical care and pharmaceutical provision”

Study discipline	Pharmaceutical Law and Legislation
Educational qualification	second (master’s) level of higher education
Branch of knowledge	22 “Healthcare”
Specialty	226 “Pharmacy, Industrial Pharmacy”
Educational program	educational-professional program “Pharmacy” for second (master’s) level of higher education, specialty 226 “Pharmacy, Industrial Pharmacy”

Approved: at the meeting of the department of forensic medicine and medical law on August 27, 2024, protocol No. 1.

Considered and approved: at the meeting of the cyclic methodical commission for natural sciences dated August 28, 2024, protocol No. 1.

The methodical development was made by **A.B. Berzina**, associate professor of the Department of Forensic Medicine and Medical Law of Bogomolets National Medical University, candidate of legal sciences, associate professor.

Type of lecture: traditional.

Competences: ability to use knowledge of regulatory and legislative acts of Ukraine and recommendations of proper pharmaceutical practices in professional activities.

Purpose: the implementation of economic activity and insurance in the field of health care should be carried out under conditions of transparency and openness, because the life and health of a person may depend on it. Therefore, it is important to determine the main problems in the field of health care at the state level and to determine the ways to their possible solution. At the same time, it is appropriate to define the main characteristics of such categories as "medical assistance" and "medical service" in order to establish the cases for which contractual liability may arise.

Lecture equipment: personal computer.

Tasks of the lecture:

1. Get acquainted with the main economic activities in the field of health care, the criteria for classifying institutions as health care institutions, licensing and accreditation of such institutions, as well as find out issues related to medical insurance in Ukraine.
2. To know and learn: the grounds and procedure for medical insurance, the basics of economic activity in the field of health care, the limits of the exercise and realization of everyone's right to medical assistance and medical services.
3. Master the skills of: using the rights and fulfilling the duties of economic entities in the field of health care; differentiation by types of medical care and medical services in the field of health care.

Lecture plan:

№	The main stages of the lecture and their content	1) Type of lecture. 2) Means of student activation. 3) Methodological support materials.	Time
1	2	3	4
1) Preparatory stage			
	Determination of relevance of the topic, educational goals of the lecture and motivation (I, II, III, IV)	Thematic lecture.	5
2) The main stage			

	<p>Plan</p> <ol style="list-style-type: none"> 1. Human health as a fundamental medical and legal category. 2. Economic activity in the sphere of health care of Ukraine. 3. Problems of reforming the healthcare system of Ukraine: advantages and disadvantages. 4. Health care institution of Ukraine as a business entity. 5. Licensing and accreditation of healthcare facilities. 6. Voluntary health insurance: state of legislative consolidation and practice of application. Problems of the establishment and development of national compulsory health insurance. 7. Concepts and signs of medical care. The right to medical assistance according to the legislation of Ukraine. 8. Medical service as an object of medical legal relations. The contract for the provision of medical services: concepts, general characteristics and features of implementation. Contractual liability in the field of health care. 	<p>Questions, problematic situations.</p>	<p>70</p>
<p>3) The final stage</p>			
	<p>Summary of the lecture, general conclusions. Answers to possible questions. Tasks for self-training of students.</p>	<p>Educational literature, tasks, questions</p>	<p>15</p>

Recommended literature

International legal standards

1. Dyrektyva 2001/83/YES Yevropeys'koho parlamentu i Rady YES vid 06.11.2001 r. «Pro zvid zakoniv Spivtovarystva shchodo likars'kykh zasobiv dlya lyudyny».
2. Yevropeys'ka sotsial'na khartiya: Rada Yevropy; Khartiya vid 18.10.1961 r. № ETS № 35. – [Elektronnyy resurs]. – Rezhym dostupu: http://zakon1.rada.gov.ua/laws/show/994_062.
3. Konventsiya pro zakhyst prav lyudyny i osnovopolozhnykh svobod: Rada Yevropy; Konventsiya vid 04.11.1950 r. – [Elektronnyy resurs] – Rezhym dostupu: http://zakon4.rada.gov.ua/laws/show/995_004.
4. Konventsiya pro pidroblennya medychnoyi produktsiyi ta podibni zlochyny, shcho zahrozhuyut' okhoroni zdorov"ya: Rada Yevropy; Konventsiya vid

28.10.2011 r. – [Elektronnyy resurs] – Rezhym dostupu: http://zakon2.rada.gov.ua/laws/show/994_a91.

National legislation

1. Hospodars'kyi kodeks Ukrainy: Kodeks Ukrainy vid 16.01.2003 r. № 436-IV (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 2003. – № 18, № 19–20, № 21–22. – St. 144.
2. Etychnyy kodeks likarya Ukrainy. – Pryynyaty ta pidpysany Vseukrayins'kym z"yizdom likars'kykh orhanizatsiy ta X Z"yizdom Vseukrayins'koho likars'koho tovarystva (VULT) vid 27 veresnya 2009 r. – [Elektronnyy resurs]. – Rezhym dostupu: <http://health-ua.com/pics/pdf/19/30-31.pdf>.
3. Kodeks Ukrainy pro administratyvni pravoporushennya: Kodeks Ukrainy vid 07.12.1984 r. № 8073-X (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy RSR. – 1984. – Dodatok do № 51. – St. 1122.
4. Konstytutsiya Ukrainy vid 28.06.1996 r. // Vidomosti Verkhovnoyi Rady Ukrainy – 1996. – № 30. – St. 141.
5. Kryminal'nyy kodeks Ukrainy: Kodeks Ukrainy vid 5 kvitnya 2001 r. (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 2001. – № 25–26. – St. 131.
6. Osnovy zakonodavstva Ukrainy pro okhoronu zdorov'ya: Zakon Ukrainy vid 19.11.1992 r. № 2801-KHII (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 1993. – № 4. – St. 19.
7. Pro dostup do publichnoyi informatsiyi: Zakon Ukrainy vid 13.01.2011 r. №2939-VI (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 2011. – № 32. – St. 314.
8. Pro zabezpechennya sanitarnoho ta epidemichnoho blahopoluchchya naselennya: Zakon Ukrainy vid 24.02.1994 r. № 4004-XII (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 1994. – № 27. – St. 218.
9. Pro zatverdzhennya Pereliku likars'kykh zasobiv, dozvolenykh do zastosuvannya v Ukraini, yaki vidpuskayut'sya bez retseptiv z aptek ta yikh strukturnykh pidrozdiliv: Nakaz Ministerstva okhorony zdorov'ya Ukrainy vid 06.12.2010 r. № 1081. – [Elektronnyy resurs]. – Rezhym dostupu: <http://zakon4.rada.gov.ua/laws/show/z1316-10>.
10. Pro zatverdzhennya Polozhennya pro Derzhavnu sluzhbu Ukrainy z likars'kykh zasobiv: Ukaz Prezydenta Ukrainy vid 08.04.2011 r. №440/2011 (iz zminamy). – [Elektronnyy resurs]. – Rezhym dostupu: <http://zakon4.rada.gov.ua/laws/show/440/2011>.
11. Pro zatverdzhennya Poryadku provedennya klinichnykh vyprobuvan' likars'kykh zasobiv ta ekspertyzy materialiv klinichnykh vyprobuvan' i Typovoho polozhennya pro komisiyi z pytan' etyky: Nakaz Ministerstva

okhorony zdorov"ya Ukrayiny vid 23.09.2009 r. № 690 (iz zminamy) // Ofitsiynyy visnyk Ukrayiny. – 2009. – № 87. – St. 2948.

12. Pro zakhyst naseleण्या vid infektsiynykh khvorob: Zakon Ukrayiny vid 06.04.2000 r. №1645–III (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2000. – № 29. – St. 228.

13. Pro zakhyst personal'nykh danykh: Zakon Ukrayiny vid 01.06.2010 r. № 2297–VI (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2010. – № 34. – St. 481.

14. Pro zakhyst prav spozhyvachiv: Zakon Ukrayiny 12.05.1991 r. № 1023–XII (iz zminamy) // Vidomosti Verkhovnoyi Rady URSR. – 1991. – № 30. – St. 379.

15. Pro Klyatvu likarya: Ukaz Prezydenta Ukrayiny vid 15.06.1992 r. № 349. – [Elektronnyy resurs]. – Rezhym dostupu: <http://zakon4.rada.gov.ua/laws/show/349/92>.

16. Pro likars'ki zasoby: Zakon Ukrayiny vid 04.04.1996 r. № 123/96-VR (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 1996. – № 22. – St. 86.

17. Pro litsenzuvannya pevnykh vydiv hospodars'koyi diyal'nosti: Zakon Ukrayiny vid 01.06.2000 r. № 1775–III // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2000. – № 36. – St. 299.

18. Pro narkotychni zasoby, psykhotropni rehovyny i prekursorsy: Zakon Ukrayiny vid 15.02.1995 r. № 60/95–VR (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2007. – № 10. – St. 89.

19. Pro polozhennya pro Ministerstvo okhorony zdorov"ya Ukrayiny: Ukaz Prezydenta Ukrayiny vid 13.04.2011 r. № 467/2011. – [Elektronnyy resurs]. – Rezhym dostupu: <http://zakon2.rada.gov.ua/laws/show/467/2011>.

20. Pro poryadok provedennya reformuvannya systemy okhorony zdorov"ya u Vinnyts'kiy, Dnipropetrovs'kiy, Donetsk'kiy oblastiakh ta misti Kyievi: Zakon Ukrayiny vid 07.07.2011 r. № 3612-VI (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2012. – № 12–13. – St. 81.

21. Pro ratyfikatsiyu Yevropeys'koyi sotsial'noyi khartiyyi (perehlyanutoyi): Zakon Ukrayiny vid 14.09.2006 r. № 137–V // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2006. – № 43. – St. 418.

22. Pro ratyfikatsiyu Konventsii Rady Yevropy pro pidroblennya medychnoyi produktsiyyi ta podibni zlochyny, shcho zahrozhuyut' okhoroni zdorov"ya: Zakon Ukrayiny vid 07.06.2012 r. № 4908–VI // Vidomosti Verkhovnoyi Rady. – 2013. – № 17. – St. 160.

23. Pro Rekomendatsiyi parlament's'kykh slukhan' na temu: «Prosuchasnyy stan ta perspektyvy rozvytku farmatsevychnoyi haluzi Ukrayiny»: Postanova Verkhovnoyi Rady Ukrayiny vid 06.10.2011 r. № 3901–VI // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2012. – № 21. – St. 205.

24. Pro rishennya Rady natsional'noyi bezpeky i oborony Ukrayiny vid 25 travnya 2012 roku «Pro zabezpechennya naseleण्या yakisnymy ta dostupnymy likars'kymy zasobamy»: Ukaz Prezydenta Ukrayiny vid 30.08.2012 r. №

526/2012. – [Elektronnyy resurs]. – Rezhym dostupu: <http://zakon4.rada.gov.ua/laws/show/n0004525-12>.

25. Tsyvil'nyy kodeks Ukrayiny: Kodeks Ukrayiny vid 16.01.2003 r. № 435–IV (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2003. – № № 40–44. – St. 356.

Recommended literature

1. Hrazhdansko-pravovye otnosheniya v farmatsevticheskom sektore Ukrayny: Konspekt lektsyy. / V.A. Shapovalova, A.S. Abrosymov, V.V. Shapovalov, N.M. Khalyn. – KH., 2002. – 17 s.
2. Lytsenzyrovanye v Evropeyskom Soyuze: farmatsevtichesky sektor / Red.-sost. V.A. Usenko, L.A. Spasokukotsky. – K.: Moryon LTD, 1998. – 384 s.
3. Pravovi osnovy diyal'nosti medychnykh i farmatsevtichnykh pratsivnykiv: navchal'nyy posibnyk / Babanin A.A., Yasins'ky V.I. – Simferopol', 2002. – 432 s.
4. Suchasne ukrayins'ke medychne pravo: Monohrafiya / Za zah. red. S.H. Stetsenka. – K.: Atika, 2010. – 496 s.
5. Farmatsevtichne zakonodavstvo Ukrayiny: Zbirnyk normatyvno-pravovykh aktiv stanom na 1 veresnya 2012 r. dlya studentiv farmatsevtichnykh fakul'tetiv / A.A. Kotvits'ka, I.V. Kubaryeva, O.O. Surikov, A.V. Volkova. / Za zah. red. prof. A.A. Kotvits'koyi. – KH.: NfaU, 2012. – 344 s.
6. Farmatsevtichne pravo. Navchal'nyy posibnyk do audytornoyi ta pozaaudytornoyi roboty z farmatsevtichnoho zakonodavstva za spetsial'nisty «Farmatsiya» / V.O. Shapovalova, V.V. Shapovalova, V.V. Shapovalov ta in. – KH., 2008. – 144 s.

Additional literature

1. Bratanyuk L.YE. Osnovy prava i zakonodavstva v okhoroni zdorov'ya: pidruchnyk. – K.: Medytsyna, 2011. – 544 s.
2. Buletsa S.B. Pravo fizychnoyi osoby na zhyttya ta zdorov'ya (porivnyal'no-pravovyy aspekt): monohrafiya / S.B. Buletsa. – Uzhhorod: Lira, 2006. – 172 s.
3. Halatsan O.V. Farmatsevtichne i medychne pravo: pro neobkhidnist' reformuvannya okhorony zdorov'ya Ukrayiny dlya pokrashchennya narkolohichnoyi ta kryminohennoyi sytuatsiyi sered naseleння / O.V. Halatsan., V.O. Shapovalova, V.V. Shapovalov // Problemy bezperervnoyi medychnoyi osvity ta nauky. – 2012. – № 3. – S. 16–18.
4. Hladun Z.S. Derzhavna polityka okhorony zdorov'ya v Ukrayini (administratyvno-pravovi problemy formuvannya i realizatsiyi): Monohrafiya. / Z.S. Hladun – Ternopil': «Ekonomichna dumka», 2005. – 460 s.
5. Hryhoryan S.L. Farmatsevticheskoe zakonodatel'stvo ES: ot pervoy dyrektyvy po sehodnyashnyy den' // Rossyyskiye apteky. – 2004. – № 11. – S. 4–6.

6. Kolyada V.V. Stanovlennya ta podal'she reformuvannya normatyvno-pravovoyi bazy, shcho rehulyuye obih narkotychnykh zasobiv, psykhotropnykh rehovyn ta prekursoriv v Ukrainy // Farmakolohichnyy visnyk. – 2000. – №6. – S. 2–7.
7. Kolyada V.V., Pastalytsa S.V. Normatyvno-pravovaya baza oborota bezretsepturnykh lekarstvennykh sredstv / Farmatsevticheskie pravo v bezopasnom samolechenyy: lekarstvennye sredstva, otpuskaemye bez retsepta vracha. – KH.: Fakt, 2005. – S. 24–29.
8. Kolyada V.V., Shapovalov V.V., Shapovalova V.O. Farmatsevtichne pravo yak osnova udoskonalennya pravyl rehulyuvannya retsepturnoho ta bezretsepturnoho vidpusku likars'kykh zasobiv v Ukrainy // Liky Ukrainy. – 2004. – №9 (dodatok). – S.82–84.
9. Maleyna M.N. Chelovek y medytyna v sovremennom prave: uchebnoe y praktycheskoe posobyе / M.N. Maleyna. – M.: BEK, 1995. – 272 s.
10. Medychne pravo Ukrainy: zakonodavche zabezpechennya tsaryny okhorony zdorov'ya (henezys, mizhnarodni standarty, tendentsiyi rozvytku y udoskonalennya). Materialy V Vseukrayins'koyi (IV Mizhnarodnoyi) naukovo-praktychnoyi konferentsiyi z medychnoho prava (19–21 travnya 2011 roku, m. Odesa) / Upor. I.YA. Senyuta, KH.YA. Tereshko. – L'viv: LOBF «Medytyna i pravo», 2011. – 416 s.
11. Pashkov V.M. Oznaky hospodars'ko-pravovykh vidnosyn pry zdiysnenni medychnoho ta farmatsevtichnoho obsluhovuvannya / V. M. Pashkov // Pidpryyemnytstvo, hospodarstvo i pravo. – 2008 (149) – № 5. – S. 53–57.
12. Pashkov V. M. Problemy pravovoho rehulyuvannya vidnosyn u sferi okhorony zdorov'ya (hospodars'ko-pravovyy kontekst) / V.M. Pashkov. – K.: MORION, 2009. – 448 s.
13. Pashkov V.M. Problemy derzhavnoho rehulyuvannya pravovidnosyn u haluzi okhorony zdorov'ya / V.M. Pashkov // Ukrainy's'kyy medychnyy chasopys. – 2005. – №5 (49). – S. 64–67.
14. Suchasne ukrayins'ke medychne pravo: monohrafiya / za zah. red. S. H. Stetsenka. – K.: Atika, 2010. – 496 s.
15. Tlumachennya norm farmatsevtichnoho prava u vidpovidnosti do yevropeys'kykh standartiv po optymizatsiyi lehal'noho obihu retsepturnykh i bezretsepturnykh likars'kykh zasobiv / V.V. Shapovalov, Z.S. Halavan, V.V. Kolyada, V.O. Shapovalova, V.V. Shapovalov // Visnyk farmakolohiyi ta farmatsiyi. – 2005. – №7. – S.27–30.
16. Shatkovs'kyy YA.M. Obov'yazkove medychne strakhuvannya v Ukrainy: pravovi problemy ta perspektyvy yikh vyrishennya / YA.M. Shatkovs'kyy // Visn. L'viv. un-tu. Ser. yurydychna. – 2008. – № 1. – S. 98–102.

Questions for student self-preparation for the lecture:

1. Human health as a fundamental medical and legal category.

2. Economic activity in the sphere of health care of Ukraine.
3. Problems of reforming the healthcare system of Ukraine: advantages and disadvantages.
4. Health care institution of Ukraine as a business entity.
5. Licensing and accreditation of healthcare facilities.
6. Voluntary health insurance: state of legislative consolidation and practice of application. Problems of the establishment and development of national compulsory health insurance.
7. Concepts and signs of medical care. The right to medical assistance according to the legislation of Ukraine.
8. Medical service as an object of medical legal relations. The contract for the provision of medical services: concepts, general characteristics and features of implementation. Contractual liability in the field of health care.

Questions for preparation for Final Control, which are revealed by the lecture material

1. How is the category of "health" defined under the legislation of Ukraine?
2. Describe economic activity in the field of health care.
3. What are the main problems in the field of health care that are most relevant in this period? What are the possible ways to solve them?
4. What is the accreditation of a health care facility?
5. What is the procedure for obtaining a health care facility license?
6. What is the current state of voluntary health insurance in Ukraine?
7. What is medical assistance and how does it differ from a medical service?
8. What are the features of contractual liability in the field of health care?