

BOGOMOLETS NATIONAL MEDICAL UNIVERSITY

Department of Forensic Medicine and Medical Law

GUIDELINES to the lecture No. 5 ON TOPIC No. 7:

«Legal regulation of the work of pharmaceutical employees. Social and legal protection of pharmaceutical employees»

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: highlighting as a separate topic the issue of legal relations in the system of legal guardianship of pharmacy specialists is necessary considering the need for the existence of a state guarantee of their protection. Pharmaceutical workers must be able to and understand the labor duties assigned to them, know their rights and the specifics of their implementation.

Lecture equipment: personal computer.

Tasks of the lecture:

1. To acquaint students with the basic conceptual apparatus in the legal field and the principles of state policy in the field of guardianship of pharmacy specialists; to determine the peculiarities of the legal regulation of the labor relations of pharmacists.
2. To know and learn the necessary conceptual minimum, without which it is impossible to form a general idea about the social guarantees of the protection of pharmacists; labor rights and responsibilities of each employee; the basics of social security of pharmaceutical workers.
3. Master the skills: freely navigate labor legislation, know about the available guarantees of social protection of pharmaceutical workers; learn to apply knowledge of pharmaceutical legislation of Ukraine in practice; master legal methods of protecting violated labor rights.

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. Legal guardianship of pharmacy specialists: concept and meaning. 2. Public protection of the rights of business entities. Appealing decisions of state supervision bodies. 3. Basic guarantees of the right to work. Labor legislation. 4. Collective agreement: the parties and the procedure for concluding it. 5. Labor discipline and methods of ensuring it. Internal labor regulations. Basic duties of the employee and the employer. 6. Normative and legal regulation of compliance with professional rights and provision of benefits for pharmaceutical workers. 7. The right to engage in pharmaceutical activity in accordance with specialty and qualification. List of provisional positions and positions of junior specialists with pharmaceutical education (pharmacists) in health care institutions. 8. Improvement of qualifications; free choice of proven forms, methods and means of activity. 	Questions, problematic situations.	70
3) The final stage			
	<p>Summary of the lecture, general conclusions. Answers to possible questions. Tasks for self-training of students.</p>	Educational literature, tasks, questions	15

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 prekursory: 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 neobkhdnist' 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 pervoyi 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 Ukrayiny // 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 Ukrayini // Liky Ukrayiny. – 2004. – №9 (dodatok). – S.82–84.
9. Maleyna M.N. Chelovek y medytsyna v sovremennom prave: uchebnoe y praktycheskoe posobyе / M.N. Maleyna. – M.: BEK, 1995. – 272 s.
10. Medychne pravo Ukrayiny: 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 «Medytsyna 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 derzhavnogo rehulyuvannya pravovidnosyn u haluzi okhorony zdorov'ya / V.M. Pashkov // Ukrayins'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 Ukrayini: 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. What is the legal guardianship of pharmacy specialists?

2. What is the public protection of the rights of business entities and in what cases is it possible to appeal the decisions of state supervision bodies?
3. What are the components of such a state guarantee as the right to work?
4. What is a collective agreement and what is the procedure for concluding it?
5. What is labor discipline and what are the methods of ensuring it?
6. Who is the subject of labor relations?
7. What professional rights do pharmaceutical workers have?
8. What are the functional duties of an employee?
9. What are working hours and rest time?
10. What are the preferential conditions of pension provision for pharmacy specialists?
11. Reveal the essence of the right to engage in pharmaceutical activity according to specialty and qualification.
12. What qualifications must a pharmacist meet?
13. What is the procedure for improving the qualifications of persons with pharmaceutical education?

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

1. Explain the meaning of the concept of "legal guardianship of pharmacy specialists".
2. What is the public protection of the rights of business entities and in what cases is it possible to appeal the decisions of state supervision bodies?
3. What are the components of such a state guarantee as the right to work?
4. What is a collective agreement and what is the procedure for concluding it?
5. What is labour discipline and what are the methods of ensuring it?
6. Who is the subject of labour relations?
7. What professional rights do pharmaceutical workers have?
8. What are the functional duties of an employee?
9. What are working hours and rest time?
10. What are the preferential conditions of pension provision for pharmacy specialists?
11. Reveal the essence of the right to engage in pharmaceutical activity according to specialty and qualification.
12. What qualifications must a pharmacist meet?
13. What is the procedure for improving the qualifications of persons with pharmaceutical education?