



## SUBJECT OUTLINE

### 1. Programme of study description

1.1.	<b>THE "CAROL DAVILA" UNIVERSITY OF MEDICINE AND PHARMACY</b>
1.2.	<b>THE FACULTY OF MEDICINE / DEPARTMENT 14</b>
1.3.	<b>DISCIPLINE: Medical Legal Elements and Malpractice</b>
1.4.	<b>DOMAIN OF STUDY: Healthcare – regulated sector within the EU</b>
1.5.	<b>CYCLE OF STUDIES: BACHELOR'S DEGREE</b>
1.6.	<b>PROGRAMME OF STUDY: MEDICINE</b>

### 2. Subject description

2.1.	<b>Name of the subject/compulsory subject/elective subject within the discipline: Medical Legal Elements and Malpractice</b>						
2.2.	<b>Location of the discipline: The Faculty of Medicine</b>						
2.3.	<b>Course tenured coordinator: Senior Lecturer Ph.D., 50 ani, 8 years experience</b>						
2.4.	<b>Practicals/clinical rotations tenured coordinator: Senior Lecturer Ph.D., 50 ani, 8 years experience</b>						
2.5. Year of study	I	2.6. Semester	I, II	2.7. Type of assessment	Written examination and practical examination	2.8. Subject classification	Mandatory

### 3. Total estimated time (hours/semester of didactic activity) – teaching module

Number of hours per week	2	Out of which: course	2 hours/week for 7 weeks	Seminar	2 hours/week for 7 weeks
Total number of hours from curriculum	28	Out of which: course	14	Seminar	14
Distribution of allotted time	14 weeks				28 Hours
Study from textbooks, courses, bibliography, and student notes					
Additional library study, study on specialized online platforms and field study					
Preparing seminars / laboratories, assignments, reports, portfolios and essays					
Tutoring					
Examinations					
Other activities					
Total hours of individual study					
Number of credit points					

### 4. Prerequisites (where applicable)

4.1. of curriculum	
4.2. of competencies	

### 5. Requirements (where applicable)

5.1. for delivering the course	Computer, video projector, amphitheater
5.2. for delivering the seminars	Students' lateness/Being late to practical work will not be tolerated as it proves disruptive to the educational process;

### 6. Acquired specific competencies

Professional competencies (expressed through knowledge and skills)	To know the concepts of medical ethics, medical legislation, patient safety and the quality of the medical act and to identify
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	<p>the differences and relationships between them.</p> <p>To know the concept of legal liability of the doctor in correlation with that of professional liability and to identify its conditions and forms.</p> <p>To know the patients' rights and the correlative obligations of the doctor and the medical institution.</p> <p>To identify the vulnerabilities of medical practice in the face of malpractice allegations and the methods of managing them.</p> <p>To identify methods of preventing medical malpractice accusations.</p>
<b>Transversal competencies (of role, of professional and personal development)</b>	<p>To identify the roles and responsibilities in a team and to apply effective communication and work techniques within the team and in relation with the patient.</p> <p>To be(come) aware of the need for continuous training for professional development.</p> <p>To possess verbal communication skills needed for teamwork and public presentations</p>

### **7. Subject learning objectives (based on the scale of acquired specific competencies)**

<b>7.1. General learning objective</b>	Acquiring the necessary knowledge and skills to manage current cases and complex, interdisciplinary situations in future medical practice in accordance with applicable legal requirements and to identify the need to develop new regulations.
<b>7.2. Specific learning objectives</b>	<p>Knowing and understanding the legal requirements to develop an efficient and safe medical practice.</p> <p>Developing a relationship with patients starting from the observance of specific rights.</p> <p>Being aware that the need to align everyday practice with specific legal requirements influences any medical decision.</p> <p>Being aware of legal liability.</p> <p>Identifying vulnerabilities in cases of medical malpractice accusations and addressing them by initiating activities.</p>

### **8. Content**

<b>8.1. Course</b>	<b>Teaching methods</b>	<b>Observations</b>
Course 1 From human rights to bioethics, medical legislation, medical malpractice and quality in medicine.	Lecture (Interactive presentation of the material according to the analytical program, using multimedia means, power point presentations)	1 lecture
Course 2 Professional liability in medical practice	Lecture (Interactive presentation of the material according to the analytical program, using multimedia means, power point presentations)	1 lecture
Course 3 Area of focus for medical law (1): informed patient consent (competence, the process of obtaining it, exceptions, scientifically unjustified refusal, legal forms)	Lecture (Interactive presentation of the material according to the analytical program, using multimedia means, power point presentations)	1 lecture
Course 4 Area of focus for medical law (2): confidentiality, patient access to their own medical data, the right to a second medical opinion, media access.	Lecture (Interactive presentation of the material according to the analytical program, using multimedia means, power point presentations)	1 lecture



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Course 5 Area of focus for medical law (3): patients' access to treatment, patient discrimination, medical practice beyond the limits of competence, participation in medical education, clinical research.	Lecture (Interactive presentation of the material according to the analytical program, using multimedia means, power point presentations)	1 lecture
Course 6 Vulnerabilities of medical practice in malpractice accusations. Risk management.	Lecture (Interactive presentation of the material according to the analytical program, using multimedia means, power point presentations)	1 lecture
Course 7 Preventing medical malpractice litigations, increasing patient safety and the medical act quality.	Lecture (Interactive presentation of the material according to the analytical program, using multimedia means, power point presentations)	1 lecture
<b>8.2. Seminars</b>	<b>Teaching methods</b>	<b>Observations</b>
S 1 Comparative analysis of the ethical, legal and qualitative requirements imposed on the medical practice.	Discussion, individual presentations	1 practical session
S2 Analysis of court rulings on medical liability in order to identify the types of the physician's legal liability. Individual liability vs. institutional liability.	Case studies, brainstorming, individual presentations	1 practical session
S3 The informed consent form - legal requirements, usage, simulation of use in medical practice, analysis of Romanian and international jurisprudence, legal consequences in case of non-compliance with the medical law.	Case studies, individual presentations, discussions, work in teams	1 practical session
S4 Analysing and debating court rulings regarding the management of medical data, the relationship with the press in cases of malpractice accusations.	Case studies, discussions	1 practical session
S5 Analysing and debating complaints solved by courts, case studies regarding the medical practice beyond the limits of competence, the patient's access to treatment, patient discrimination, participation involvement in the medical education process, analysis of the required legal forms.	Case studies	1 practical session
S6 Identifying procedural differences between the different ways of legal liability, analysis of professional civil liability insurance contracts, communication with the patient, the medical institution and with third parties in the case malpractice claim.	Case studies, individual presentations, discussions, discussions, brainstorming	1 practical session



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S7 Methods of preventing medical malpractice accusations, medical practice compliance with the qualitative and legal requirements regarding the patient's rights.	Case studies, role-play	1 practical session
<b>Bibliography for course and seminars</b> Codul de deontologie medicala al Colegiului Medicilor din România; Legea 95/2006 privind reforma în domeniul sănătății modificată și completată; Legea nr.584 din 29 octombrie 2002 privind măsurile de prevenire a răspândirii maladii SIDA în România și de protecție a persoanelor infectate cu HIV sau bolnave de SIDA; Michael Preston-Shoot & Judy McKimm, „Towards effective outcomes in teaching, learning and assessment of law in medical education”, Medical Education 2011: 45: 339–346; Noul Cod Civil republicat 2011. Legea 287/2009 privind Codul civil; Nanu A., Malpraxisul medical – 7 instructiuni de siguranta, ed. Lidana, ISBN 978-606-8160-60-3,2012; Nanu A., teza de doctorat „Malpraxisul - consecințe și impact în plan moral și juridic asupra practicii medicale din România”, Academia Romana, 2008; Nanu A., Georgescu Diana., Voicu V., Ioan Beatrice., “Locul și relevanța prevederilor legale în contextul practicii medicale din România”, Revista Română de Bioetică, Vol. 9, Nr. 4, 2011; Ordinul MS nr. 1411/2016 privind aprobarea Normelor metodologice de aplicare a titlului XVI "Răspunderea civilă a personalului medical și a furnizorului de produse și servicii medicale, sanitare și farmaceutice" din Legea nr. 95/2006 privind reforma în domeniul sănătății; Ordinul MS nr. 1410 /2016 privind aprobarea Normelor de aplicare a Legii drepturilor pacientului nr. 46/2003; Ordinul MS nr. 446/2017 din 18 aprilie 2017 privind aprobarea Standardelor, Procedurii și metodologiei de evaluare și acreditare a spitalelor; Regulamentul de organizare și functionare a comisiei de monitorizare și competența profesională pentru cazurile de malpraxis, aprobat prin Ordinul ministrului sanatații publice nr. 1.343/2006; Beatrice I, Nanu A., Rotariu I., Raspunderea profesionala in practica medicala, ed. Junimea, 2017; Stan C., “Malpraxisul medical”, ISBN 978-973-1795-11-9, 2000; Steinert Y1, Mann K, Centeno A, Dolmans D, Spencer J, Gelula M, Prideaux D.: „A systematic review of faculty development initiatives designed to improve teaching effectiveness in medical education: BEME Guide No. 8.”, Med Teach. 2006 Sep;28(6):497-526; Teaching medical ethics and law within medical education: a model for the UK core curriculum, Journal of Medical Ethics 1998;24:188-192.		

**9. Corroboration of the subject content with the expectations of the representatives of the epistemic community, professional associations, and major employers in the field of the programme of study**

The development of contents and the choice of teaching methods are based on the identification of the insight and skills necessary to align medical practice with the applicable legal and qualitative requirements following the analysis of similar study programs at the international level and the development of an extensive research and training program in the field of medical legislation and malpractice addressed to Romanian licensed doctors and organized in partnership with the Romanian College of Physicians.

**10. Assessment**

Type of activity	Assessment criteria	Assessment methods	Assessment weighting within the final grade
Course	Knowing the terminology used; Understanding the legal concepts presented; The ability to apply the acquired knowledge for aligning the medical practice with the law	Written test	70%



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<b>Seminars</b>	Mastering the cases and topics discussed during courses and practical sessions; The ability to identify the proper behaviour/ conduct to be adopted in specific circumstances; The ability to properly use the legal/authorised documents required for medical practice.	Practical exam	30%
<b>Minimum performance standard</b>			
<ul style="list-style-type: none"><li>• Minimum 50% for each component of the assessment</li></ul>			

**Date of filing**  
**20.10.2022**

**Signature of the course tenured coordinator**

**Signature of the seminar tenured coordinator**

**Date of approval in the Council of the Department:**

**Signature of the Head of the Department**