

"Carol Davila" University of Medicine and Pharmacy Quality Assurance Committee

COURSE SYLLABUS

1. Program identification details

1.1.	"CAROL DAVILA" UNIVERSITY OF MEDICINE AND PHARMACY
1.2.	FACULTY OF MEDICINE
1.3.	DEPARTMENT: 14 ORTHOPEDICS/ICU
1.4.	COURSE TITLE: MEDICAL LEGAL ELEMENTS AND MALPRACTICE
1.5.	FIELD OF STUDY: HEALTH – Sectorally regulated within the European Union
1.6.	CYCLE OF STUDIES (DEGREE): BACHELOR'S DEGREE
1.7.	DEGREE PROGRAME: MEDICINE – ENGLISH MODULE

2. 2. Course identification details

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2.1.	Course title: MEDICAL LEGAL ELEMENTS AND MALPRACTICE							
2.2.	Disciplin	ne code:						
2.3.	Disciplin	ie type (FD/SD/CD): DS					
2.4.	Disciplin	ne regim	en (MD/OPD/): D	OB				
2.5.	Instruct	or						
	1. A	ssoc. Pr	of. Nanu Codrut A	Andrei				
	2. L	ecturer	Plaiasu Maria Cri	istina				
2.6.	Seminar facilitators:							
	1. Assoc. Prof. Nanu Codrut Andrei							
	2. Lecturer Plăiașu Maria Cristina							
	3. Assistant Lecturer Patpaiac Sevastian Teodor							
	4. Assistant Lecturer Banu Octavian Gabriel							
	5. Assistant Lecturer Cristina Lungu							
2.7. Y	2.7. Year of I 2.8. Semester I, II 2.9. Type of Written exam and							
study evaluation practical example of the study evaluation evaluation evaluation example of the study evaluation evaluati				practical exam				
	(E/C)							

3. Estimated workload (hours/semester for didactic activity and individual preparation/study)

I. Academic training (teaching, practical application, assessment)						
3.1. Number of hours/week	2	of which:	3.2. cours	1	3.3. seminar/ laboratory	1
3.4. Total number of teaching hours within the program	28	of which:	3.5. cours e	14	3.6. seminar/ laboratory	14
Evaluation (number of hours): 5						
II. Individual prepa	ration/stu	dy: 30				
Time Pool Distribution					hours	
Individual study of textbooks, handbooks/reader, recommended bibliography and notes study						15
Additional research (library, electronic resources, potential fieldwork) 10						10

Carrying out specific activities of preparat preparation of assignments, reports	ion for the project, laboratory,	
Preparation for presentations, final examin	nation	7
Tutoring		
Other activities		
3.7. Total individual study hours		32
3.9. Total hours per semester (3.4.+3.7.) 60		
3.10. Number of credits 3		

4. Preconditions (if necessary)

4.1. of curriculum	
4.2. of competences	

5. Conditions (if necessary)

5.1. to conduct the lecture	PowerPoint presentations, use of multimedia
	systems, and projector
5.2. to conduct the seminar / laboratory	Equipped with the necessary technology for
	practical activities

6. Learning outcomes

Knowledge	Skills	Responsibility and autonomy
The student/graduate	The student/graduate applies the	The student/graduate uses their
describes, defines and	concepts in a way that honors	own knowledge and experiences
discusses fundamental	the fundamental social values	in the medical education process
principles of social and legal	(life, health, bodily integrity)	
responsibility		
The student/graduate uses	The student/graduate correctly	The student/graduate applies the
specific terminology of the	defines and describes concepts	concepts learned in other
medical liability field	regarding the professional	medical educational courses
	liability of the physician	
The student/graduate describes	The student/graduate correctly	The student/graduate applies the
and identifies the legislative	identifies in the legislation,	concepts studies throughout their
framework of patient's rights	defines and describes the	university training in the
	patient's rights	interaction with patients
The student/graduate describes	The student/graduate correctly	The student/graduate evaluates
and identifies the legal	identifies and applies methods	and takes responsibility for their
obligations of the doctor	of aligning medical practice	behavior in the future patient-
	with specific legal requirements	doctor interaction
The student/graduate describes	The student/graduate correctly	The student/graduate integrates
the situations in which the	interprets the limits of the	individual and institutional
doctor can be exonerated from	individual liability of the	responsibility into a unitary
medical civil liability	physician	model of practice
The student/graduate	The student/graduate identifies	The student/graduate evaluates
describes, explains and	the limits of the insurance	and argues the effects of the
analyzes the role of	contracts.	medical professional liability
professional civil liability		insurance contracts
insurance		

7. Course objectives (aligned with the learning outcomes)

7.1. General objective	Assimilation of vital knowledge and skills for the management of			
	current cases and complex situations of medical practice, in			
	accordance with the legal provisions			
7.2. Specific objective	To acquire an in-depth knowledge and a clear understanding of the			
	legal requirements to develop an effective and safe medical practice.			

8. Contents

8.1. Lecture	Teaching methods	Observations
Lecture 1: The Concept of Professional Responsibility and its Implications for Medical Practice Lecture 2: Areas of application of medical legislation – Informed patient consent • Patient competence • The process of obtaining the consent • Exceptions • Unjustified scientific refusal • Legal Formulation	Lecture – interactive presentation of the material, according to the curriculum, with the use of multimedia means (PowerPoint presentations, visual materials, digital resources). Lecture – interactive presentation of the material, according to the curriculum, with the use of multimedia means (PowerPoint presentations, visual materials, digital resources).	1 lecture 1 lecture
Lecture 3: Areas of application of medical legislation – Privacy and patient rights • Privacy of medical data • Patient access to their own medical data • Right to a second medical opinion • Media access to medical information	Lecture – interactive presentation of the material, according to the curriculum, with the use of multimedia means (PowerPoint presentations, visual materials, digital resources).	1 lecture
Lecture 4: Areas of application of medical legislation – Rights and limits in the exercise of the medical profession Topics addressed: • Regulations regarding patients' fair access to treatment; • The principle of non-discrimination in medical practice;	Lecture – interactive presentation of the material, according to the curriculum, with the use of multimedia means (PowerPoint presentations, visual materials, digital resources).	1 lecture

 Legal restrictions on carrying out the medical act exclusively within one's own specialty; Legal implications of doctors' participation in medical education activities. 		
Lecture 5: Malpractice and risk management (vulnerabilities, risk management, liability insurance).	Lecture – interactive presentation of the material, according to the curriculum, with the use of multimedia means (PowerPoint presentations, visual materials, digital resources).	1 lecture
Lecture 6: The Role of Clinical Guidelines and the New Challenges of Medical Practice • The role of clinical guidelines in regulating medical practice • Legal implications of telemedicine • Legal implications of the use of artificial intelligence in medicine	Lecture – interactive presentation of the material, according to the curriculum, with the use of multimedia means (PowerPoint presentations, visual materials, digital resources).	1 lecture
Lecture 7: Legal mechanisms for exonerating the doctor's professional civil liability and analysis of contemporary doctrinal trends.	Lecture – interactive presentation of the material, according to the curriculum, with the use of multimedia means (PowerPoint presentations, visual materials, digital resources).	1 lecture
D (DTP)		
Recent Bibliography 8.2. Seminar/practical training	Teaching methods	Observations
S 1	Case studies, brainstorming, individual presentations	1 LP session
S 2 Consent form – legal requirements, usage, simulation of use in the process of obtaining consent, analysis of national (Romanian) and international jurisprudence regarding the legal consequences of the lack of consent.	Case studies, individual presentations, debate, teamwork.	1 LP session
S 3 Analysis of and comments on legal cases solved by the courts regarding the management of medical data, the relationship with the press in case of a malpractice charge S 4	Case studies, debate	1 LP session

medical practice to one's own specialty, analysis of administrative acts/customs regarding patients' access to treatment, discrimination, participation in medical		
education.		
Identifying the procedural differences between the various ways of incurring legal liability, analysis of professional liability insurance models, communication with the patient, the medical institution and third parties in the event of an accusation of malpractice	Case studies, debate	1 LP session
S6 Analysis of types of clinical guidelines and operational procedures. Case studies on telemedicine and AI.	Case studies, debate	1 LP session
S7 Analysis of examples from national (Romanian) and international doctrine and caselaw regarding the extent of the doctor's legal liability	Case studies, debate	1 LP session

Recent course and seminar bibliography

The Code of Medical Ethics of the Romanian College of Physicians

Kuglay I., Criminal Liability for Medical Malpractice, C.H. Beck, 2021

Law 95/2006 on health reform, amended and supplemented

Michael Preston-Shoot & Judy McKimm, "Towards effective outcomes in teaching, learning and assessment of law in medical education", Medical Education 2011: 45: 339–346

New Civil Code republished 2011. Law 287/2009 on the Civil Code

Nanu A., Medical Malpractice – 7 Safety Instructions, ed. Lidana, ISBN 978-606-8160-60-3,2012

Nanu, R., Practical guide on the liability for malpractice of doctors in case of using robots with artificial intelligence, Universul Judridic, Bucharest, 2024

Nasui G., Medical Malpractice – the particularities of medical civil liability, relevant internal jurisprudence, malpractice of liberal professions, ed. III, Judridic Universe, Bucharest, 2024

MS Order no. 1411/2016 regarding the approval of the Methodological Norms for the application of Title XVI "Civil liability of medical personnel and of the provider of medical, sanitary and pharmaceutical products and services" of Law no. 95/2006 on health reform

MS Order no. 1410/2016 on the approval of the Norms for the application of the Patient Rights Law no. 46/2003

MS Order no. 446/2017 of April 18, 2017 regarding the approval of the Standards, Procedure and Methodology for the evaluation and accreditation of hospitals

The Regulation on the organization and functioning of the monitoring and professional competence commission for malpractice cases, approved by the Order of the Minister of Public Health no. 1.343/2006, Beatrice I, Nanu A., Rotariu I., Professional Liability in Medical Practice, ed. Junimea, 2017

Pena A., Medical Malpractice – National and European Jurisprudence, Universul Judridic, Bucharest, 2024 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.

Tanase A., Civil liability for medical malpractice, Universul Judridic, Bucharest, 2024

Teaching medical ethics and law within medical education: a model for the UK core curriculum, Journal of Medical Ethics 1998; 24:188-192

Theisler C., Maximum Malpractice Protection, Ayer Publishing, 2020

9. Evaluation

Activity type	9.1. Evaluation criteria	9.2. Evaluation methods	9.3. Percentage in the final grade
9.4. Lecture	Knowledge of the terminology used; Understanding the legal concepts presented; Ability to apply the knowledge gained to align the practice with applicable legal requirements	Written exam (30 simple complement questions)	70%
9.5. Seminar/ practical activity	Appropriation of the concepts explained during the course and the practical sessions; The ability to identify the proper conduct to be followed in particular situations; The ability to correctly use the legal documents necessary for the practice	Practical exam in front of the group assistant (analysis of a case study according to the topics discussed, individual presentation of the conclusions)	30%
9.5.1. Individual project (if any)	-	-	-
1 0	nance standard: Minimum	50% for each component of t	he accecement

Completion date:

Signature of the instructor
Associate Professor
Nanu Codruţ-Andrei

Signature of seminar facilitator
Associate Professor
Nanu Codruţ-Andrei

Approval date by the Department Council:

Signature of the Department Director Professor Rădulescu Adrian Radu