

Health Law for Non-Lawyers Syllabus

Credit Hours: 2

Contact Information

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Course Information

Brief Description of Course

This course is an introduction to health law for non-lawyers. It will introduce health care professionals to important aspects of the legal structure of the US health care system. Topics covered will include major federal statutes affecting health care (Medicare, Medicaid, ACA, EMTALA, ADA, GINA) and recent developments concerning these statutes, confidentiality and privacy, tort litigation and malpractice, non-discrimination and the duty to treat, the regulation of drugs and devices, and law and covid-19.

Course Goals

As a result of successfully completing Health Law for Non-Lawyers, students will be able to:

- 1. Understand important similarities and differences in how health care professions and lawyers analyze problems
- 2. Describe the basic structures of law in the US (federalism; constitutional, statutory, administrative, and case law) as they impact health care
- 3. Assess how law is affected by, affects, and responds to developments in the biosciences
- 4. Summarize basic aspects of major federal statutes affecting the financing and delivery of health care (including Medicare, Medicaid, ACA, EMTALA, GINA, HIPAA)
- 5. Recognize selected aspects of state law, including malpractice law, the law of informed consent, and privacy law

Course Format & Schedule

Timeline

April 13-May 15

The course is asynchronous. Students will be required to do the readings and listen to relevant podcasts, work through the assignments, and meet 4 times (to be scheduled at students' convenience; may be individual or group) with the instructor. Links to short podcasts will be added for units. Approximately 12 hours per week for 4 weeks.

Educational and Instructional Modalities

As an example...

Modality	Percentage
Self-study	50%
Discussion with	20%
instructor	
Problem solving	30%

Role of the Student in this Course

Students will be expected to do the required reading and assignments. Students will be



expected to schedule 4 meetings with the instructor during the time frame of the class.

Required Textbook(s)/Readings

Book Title + ISBN	Author/Publisher/Edition	Approximate Cost
All required readings are available on canvas in the assigned modules		

Additional Resources

No additional resources are required for this class

Assessment & Grading

Grading Criteria

IF YOU ARE IN A PROGRAM WHERE GRADING IS PASS/FAIL, THE FOLLOWING CRITERIA WILL APPLY:

PASS. A student who completes the assignments satisfactorily, attends class as required (or submits up to two make up assignments for missed classes), and participates in discussion will receive a grade of PASS for this class. A "1" for each assignment constitutes satisfactory completion of that assignment.

FAIL: A student who fails to achieve the criteria for PASS will be assigned a grade of FAIL for the course. IF YOU ARE IN A PROGRAM REQUIRING A LETTER GRADE, THE FOLLOWING CRITERIA WILL APPLY:

A: A student who submits thoughtful responses to each assignment, and participates at least once in the discussion for each class (or submits up to two satisfactory makeup assignments), will receive a grade of A for the class. A student who submits thoughtful assignments but does not participate in two or more classes (or submit up to two satisfactory make up assignments) will receive a grade of A- for the class.

B: A student who completes the assignments satisfactorily and participates in discussion in at least 4 classes (or submits up to two satisfactory make up assignments) will receive a grade of B+ for the class. A student who completes all assignments (or makeups) satisfactorily and does not participate in discussions will receive a B.

Students who do not complete assignments or required makeups satisfactorily will not receive a passing grade. Please note that "participates in discussion" includes both making comments and asking questions (including questions such as: "I did not understand this; please explain!")

Grading System

Students will receive a final letter grade or a grade of PASS (P), or FAIL (F) for this course, depending on the program in which they are enrolled.

Student Feedback

Student feedback is an important aspect of curriculum quality improvement. Thus, students are expected to complete all assigned feedback surveys specific to a course by the due date.

Standard Policies

Please refer to the Student Handbook (on the Student Affair's website) for these policies:

Accommodations Addressing Sexual Misconduct Attendance policy Dress Code Examination and Grading Policies



Grade or Score Appeal Professionalism, Roles & Responsibilities Mistreatment

Alternate Name and/or Personal Pronoun

Class rosters are provided to the instructor with the student's legal name as well as 'Preferred' first name (if previously entered by you in the Student Profile section of your CIS account). While CIS refers to this as merely a preference, we will honor you by referring to you with the name and pronoun that feels best for you in class, on papers, exams, group projects, etc. Please advise us of any name or pronoun changes (and please update CIS) so we can help create a learning environment in which you, your name, and your pronoun will be respected.

Center for Disability & Access Services

The School of Medicine seeks to provide equal access to its programs, services and activities for all medical students. The Center for Disability and Access (CDA) provides accommodations and support for the educational development of medical students with disabilities. Medical students with a documented disability and students seeking to establish the existence of a disability and to request accommodation are required to meet with the CDA Director for recommended accommodations. The CDA will work closely with eligible students and the Academic Success Program to make arrangements for approved accommodations. The School of Medicine and CDA maintain a collegial, cooperative, and collaborative relationship to ensure compliance with federal and state regulations for students with disabilities.

Steven Baumann EdD, School of Medicine Senior Director of Academic Success Program, serves as the liaison between the School of Medicine and the CDA.

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University of Utah Center for Disability and Access Olpin Student Union Building, Room 162 Phone (Voice/TDD): (801) 581-5020 <u>http://disability.utah.edu</u>

Class sessions and assignments

#1. Introduction to Health Law for Non-lawyers

Objectives:

--to consider perceptions about law among students in the course; what background do students have? What do they know and want to know about law?

--to discuss similarities and differences between how health care professionals and lawyers analyze problems. For example, is the logical structure of a differential diagnosis like, or unlike, a lawyer's analysis of a case?



--to understand the basics of the U.S. constitutional system: federal enumerated powers (especially interstate commerce) and fundamental rights (especially free speech, free exercise, liberty)

Reading: Constitutional law file, in Module #1.

#2. Tort law: malpractice and emerging issues, including disclosure of genetic risk to family members, apologies, and telemedicine

Objectives:

--to understand the basic structure of medical malpractice law

--to understand the challenges for tort law of new developments in medicine such as the growing role of genetic information and precision medicine, or the use of telemedicine

--to consider how the law affects how providers approach mistakes

--to consider the differences between tort law and regulation (for example, rules about licensing) as ways to incentivize quality of care

Outline.

(1) Please read Swan v. Lamb as an example of a medical malpractice decision.

(2) Pate v. Threlkel and Safer v. Pack represent differing approaches to whether

providers have a duty to disclose genetic risks to family members of their patients. Notably these cases were decided in 1995 and 1996, over twenty years ago. Since then, there have been few legal decisions on the duty to warn despite the massive developments concerning the role of genetics in health care. We'll begin by discussing the problems raised by these cases and whether it would be desirable to recognize a duty to warn of genetic risk. We'll also ask whether duties to warn might be different for physicians and pharmacists, and what the differences might be.

(3) The law of evidence has traditionally held that statements against interest are admissible into evidence, based on the idea that they are likely to be true (why would you say that, if against your interest?). This rule made it difficult for providers to talk to patients about mistakes. Apology statutes try to address this difficulty. Are they a good idea? Why or why not?

(4) Telemedicine is a major new development in health care—both for physicians and for pharmacies. We'll discuss different approaches to ensuring quality of care in this new domain.

Readings:

On medical malpractice: *Swan v. Lamb* On genetic risks: *Pate v. Threlkel Safer v. Pack* On apologies: Apology packet: Utah Code On telemedicine AMA telemedicine

How does the court define the standard of care in *Swan v. Lamb*? Why do you think the concurring justices wrote separately? Explain briefly.



#3. Duties to treat (including EMTALA); health care financing (including Medicare and Medicaid); non-discrimination law as it affects health care

Objectives:

--to understand the contract law basis for establishing the provider-patient relationship

--to understand the structure of EMTALA and the limited duty to treat that it creates --to understand the basic structure of Medicare, Medicaid, and health insurance as

vehicles for paying for health care

--to understand how federal non-discrimination law affects provider choices about patient selection

Questions for thought as you read: (1) someone comes to the ED with a mild cough because he's concerned about covid-19. Can the ED turn him away because he doesn't seem sick? (2) someone comes to the ED with a serious cough and a high fever. Can the ED tell him to go instead to a different facility that has isolation capabilities?

Readings:

Introductory note Hurley v. Eddingfield Wilmington General Hospital v. Manlove (edited) Emergency Medical Treatment and Active Labor Act US government Medicare/Medicaid Can Work be Required in the Medicaid Program? Nondiscriminationhealth Discrimination at the Doctor's Office

#4. Confidentiality, public health and data use

Objectives:

--to understand the basics of the HIPAA privacy rule

--to consider statutory duties to report

--to understand the basics of the common law duty of confidentiaity

Readings:

HHS Corona Utah State Code and regulations—communicable disease reporting Francis et al. Clinician's Guide *Lawson v. Halpern-Reiss* (excerpts) HIPAA Administrative Simplification



Problem #1: You are the treating physician for two sisters. Unfortunately, one of the sisters wants nothing to do with the rest of the family; their parents refused to pay for any education for her beyond high school (although they paid for college for her younger siblings) and she

believes that she has been wronged by how her family has treated her. This estranged sister (age 42) has just been diagnosed with an aggressive stage-4 breast cancer; genetic analysis reveals that she has a deleterious variant of the BRCA-1 gene. She is adamant that the information not be shared with family members—she says that this is just another way that her family membership has messed her up and it will serve them right if they are messed up too. May you use the information you know from her treatment in the care of her siblings, trying to do so in a way that does not reveal her diagnosis to them?

Problem #2: You are an oncologist treating a 15-year old patient with widely metastatic sarcoma. The patient is hospitalized and you do not believe he has long to live as his lung function is deteriorating rapidly. His parents refuse to tell him that his condition is terminal—and they are insistent that no one on the staff should share the information with him either. Their reasoning is that if he is told that his cancer has returned, he will give up hope and stop fighting. They think that their son is a fighter and they are praying for a miracle. What are you legally permitted to do if your patient asks you if he is dying?

#5. FDA regulation; access to medications

Objectives:

--to understand how the process of FDA drug approval works --to understand the relationship between the FDA drug approval process and "right to try" laws

--to discuss the likely impact of right to try laws and their advantages and disadvantages

For thought: Given the tradeoffs (to safety/efficacy, and access) discussed in the readings for today, would you have granted the Abigail Alliance access to the unapproved drug? Should people have ready access to unapproved drugs for covid-19?

Readings:

Abigail Alliance

FDA Approval, Kickbacks and Conflicts of Interest in the Marketing of Prescription Pain Meds



Utah Right to Try Act

Federal Right-to-Try Legislation—Threatening the FDA's Public Health Mission

#6. Reproduction; abortion and surrogacy

Objectives

--to understand the changing constitutional law landscape regarding abortion

--to understand state law about parents and parental responsibility

--to understand state law about surrogacy contracts

Reading:

--Introductory materials for reproduction

--Whole Women's Health v. Hellerstedt (excerpts)

--In re Gestational Agreement.doc

#7. Informed consent, Decision-making capacity; law and the end of life

Objectives

--to understand capacity, competence, and the difference between them

--to understand advance directives

--to understand aid-in-dying legislation

Reading

Introductory material Northern case Appelbaum pdf Cruzan decision

#8. Law and crises: opioids and covid-19

Objectives

--to understand the role of law in the opioid crisis

--to understand legal aspects of the covid-19 pandemic

Reading

--FDA approval, kickbacks and conflicts of interest in the marketing of prescription pain meds

--covid-19 materials