**HEALTH LAW SURVEY**

**Spring 2024**

**Law 6930/19365**

**Professor:** Barbara J. Evans (FACULTY)

**Credits:** 3 **Course Area:** Health Law

**Time:** TW 9-10:25, **Room:** Hol 355D

**SYLLABUS Version 1 of 1-4-2024 and COURSE POLICIES (see p. 7)**

**Professor Barbara J. Evans Office Hours: MT 10:30-11:30 and by request**

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**This Syllabus and Reading List (pages 1 – 6 of this document) focuses on substantive course content and readings.** The **Resources and Course Policies** document, starting on page 7, offers additional information about the conduct of the class, testing, resources for students, and the rules and norms of civility expected in class.

Note: Topics to be covered are as shown in this syllabus and will be covered in the order shown. The pace at which we move through topics may be adjusted as the course progresses, because I sometimes adjust the pace to ensure your mastery of the material. Any adjustments or revisions will be announced in class or electronically on Canvas.

**Brief course description.** This course provides a practice-oriented introductory tour of key state/federal laws governing health-sector businesses, which together account for 18% U.S. Gross Domestic Product. The course covers traditional 20th-century healthcare institutions such as hospitals, but also introduces the expanding array of new players that supply innovative products and services (clinical laboratories; medical software vendors, biobanks; and academic medical centers which conduct research as well as providing patient care) These latter entities are a vibrant and growing part of the health industry and students entering the health law workforce of today need to know the laws that affect them.

The broader goals of this course are to acquaint students with the core corporate client base for large-firm and in-house health lawyers; to introduce major regulatory frameworks that struggle to safeguard consumers’ rights vis-à-vis commercial health-sector enterprises; and to identify big, unsettled questions likely to generate opportunities for practical, solution-oriented lawyers as this staid and troubled industry gropes for new business models in the age of AI-enabled health care.

**Specific learning objectives are noted in each section of the syllabus.**

**Prerequisites.** No prerequisites are required other than completion of 1L courses. This course is suitable as an overview for students aiming to specialize in health law. It also is suitable as an elective for anybody who may – whether as an employer or as a patient – have future dealings with health insurers and healthcare providers, or who may wish to be a more informed participant in the ongoing policy debates about the structure and cost of U.S. health care.

**Evaluation/Grading.** There will be one open book/open notes 75-minute-long Midterm, which will be taken remotely at a time of your choosing during a several-day window just before Spring Break. Spring Break is March 11 – 15, so that would put the midterm in the week before that. The midterm counts for 40% of your grade. Then, there is a 1 hour, 45-minute-long Final Exam that counts for the other 60%. The final will also be offered remotely during the final exam period. The Final Exam will focus exclusively on the materials covered in the second half of the course. Material covered on the Midterm will not be covered again on the Final Exam.

The law school policy on exam delays and accommodations can be found [here](http://www.law.ufl.edu/student-affairs/current-students/forms-applications/exam-delays-accommodations-form).

**Materials.** There is no assigned book. All reading materials (including cases, key statutes and regulations, policy documents) will be posted on Canvas, along with problem sets and copies of any powerpoint slides presented in class. All posted materials used in this course are non-copyrighted (e.g., government documents or open-access articles and reports) or will be copies of materials to which you have access rights under your Westlaw subscription (However, I will post them in sequence to Canvas for your convenience). In particular, this course relies on:

The American Health Lawyers Association Health Law Practice Guide (Thomson-West) Syllabus abbreviation: **HLPG** (*available free via your student Westlaw account*). This excellent treatise, written by leading practitioners, provides a clear, straightforward, practice-oriented, and surprisingly interesting introduction to the complex tangle of laws and regulations that makes our healthcare system work the way it does (or does not) work today.

Institute of Medicine and governmental reports: These provide excellent sources of information about specific topics in the healthcare industry

**READING LIST**

**I. Introductory Matters**

Objectives: After this unit, you will be able to describe

1. Who are the main players that provide healthcare and how is healthcare financed?

1. What are the basic tension between cost containment and quality of care

**Class 1. First Day (Tuesday, Jan. 16)**

**Before class read R1 and R2**

**R1. Atul Gawande**, *The Cost Conundrum*, New Yorker, June 1, 2009,

 [www.newyorker.com/reporting/2009/06/01/090601fa\_fact\_gawande](http://www.newyorker.com/reporting/2009/06/01/090601fa_fact_gawande)

**R2. Wickline v. State (California)**

 Also: read course policies for this course at end of this Syllabus

**Class 2 (Jan. 17) Intro to Health Policy Challenges**

Before Class 2, read R3

**R3. IOM Best Care at Lower Cost Summary (Read pages 5 – 32 only)**

R4. Powerpoints will be posted on Canvas, but you need not look at them before class

**Class 3 (Jan 23). Intro to Players in the Health Care Industry**

Before Class 3, read R5, R6

**R5. AHLA HLPG Sec. 1 Healthcare Providers**

**R6. AHLA HLPG Sec. 18 – 20 Payers and Medicare**

**II. Evolution of relationships between Physicians and Hospitals and Liability of Hospitals for a Physician’s Tort**

Objectives. After this unit, you will be able to:

1. Explain the traditional relationship between healthcare professionals and healthcare institutions (hospitals) and how it has evolved.
2. Described the Corporate Practice of Medicine doctrine that is still followed in a minority of states, but they are big states that have a large impact on the healthcare industry (e.g., California, Texas
3. Sidestep the deal-destroying impact the Corporate Practice of Medicine doctrine can have on modern healthcare transactions, even when your own state that does not follow it.
4. Understand why doctors usually are not employees of the hospitals where they work
5. Apply modern concepts for holding hospitals and managed care organizations accountable for deficiencies in care caused by physicians.
6. Describe the governance and oversight arrangements that are in place for managing the safety and quality of non-employee physicians in healthcare organizations.

**Classes 4, 5 (Jan 24, Jan 30) Corporate Practice of Medicine Doctrine**

R7. Chase Lubitz 40 Vanderbilt Law Review 445 (1987) (excerpts)

R8. Modern Trend: Berlin v. Sarah Bush Lincoln Health Center

R9. Traditional CPM: Flynn Bros. v. First Medical Associates

R10. CPM In-class practice problem for Class 5.

**Class 6 (Jan 31, Feb 6) Medical Staff and Bylaws; Hospital Liability for Physicians’ Torts**

R11. AHLA HLPG Sec. 2 Medical Staff and Bylaws

R12. Supplement on Institutional Liability

R13 Adamski v Tacoma General Hospital (1978)

R14 Roessler v. Novak (2003)

**Class 7 (Feb 7, extending into part of Feb 13 if necessary) Hospital Liability for Physicians’ Torts, cont’d**

R15 Baptist Memorial Hospital v. Sampson (1998) (example of state rejecting apparent agency theory)

R16 St. Joseph’s Hospital v. Wolf (example of complex multi-hospital suits) This is a hard case, but it provides a laundry list of the various doctrines state courts apply in complex cases involving claims and counterclaims among multiple healthcare organizations over the alleged malpractice of a physician associated with more than one of the healthcare institutions involved.

**Class 8 (Feb 13 and part of Feb 14) Credentialing of Staff, Peer Review, and Liabilities Related to Credentialing**

R17 AHLA HLPG Sec. 2 Medical Staff, Bylaws, Hospital Accreditation & Licensure, Health Care Quality Improvement Act (HCQIA)

R18 SUPPLEMENT: Basic Defamation Law

R19 Johnson v. Misericordia excerpts (classic example of negligent credentialing)

**Class 9 (Feb 14) Suits for negligent credentialing, cont’d. Immunities under HCQIA**

R20 Poliner case – 5th circuit appeal

R21 SUPPLEMENT – HCQIA 42 USC Sec. 11101-11152

R22 In-class problems for analysis

**Class 10 (Feb 20, 21) Reporting Bad Physicians: The National Practitioner Data Bank (NPDB)**

R23 NPDB Guidebook – 2018 ed. (Look through Ch. A – E before class)

R24 In class NPDB problem-solving

**Class 11 (Feb 27) Standardizing Clinical Practice Through Guidelines**

R25 Clinical Practice Guidelines-Mello-van Tassel-IOM excerpts

Readings from: Michelle Mello on customary vs. reasonable standard of care; Katharine Van Tassel, *Harmonizing the Affordable Care Act with the Three Main National Systems for Healthcare Quality Improvement: The Tort, Licensure, and Hospital Peer Review Hearing Systems*, 78 Brook. L. Rev. 883 (2013) *excerpt;* and Institute of Medicine Report on conflicts of interest in the development of Clinical Practice Guidelines

R26 IOM Conflict of Interest standards and quality measures

R27 In class problem on COI standards for Practice Guideline Development

**Class 12 (Feb 28) Reform Efforts under the Affordable Care Act**

R28 Barry Furrow: Regulation of Patient Safety

**This concludes the materials to be covered on the midterm examination**

**REVIEW (Mar 5, March 6).**

R29 Work through the sample Midterm problems posted on Canvas

**The Midterm will be administered in remote (online) format in the latter part of the week before Spring Break. There will be a flexible time window of several days, starting after class on March 6. You can take the 75-minute Midterm at a time of your choosing during that window, which means you have an opportunity to plan your preferred time to take it. Absent a bona fide, unforeseeable circumstance such as an illness lasting several days, all students should aim to complete their Midterm Exams before Spring Break.**

**Topic: Fraud and Abuse**

**Class 13, 14 (Mar. 19). Intro to Waste, Corruption, and Fraud in Health Care**

You don’t need to look at these slides ahead of class. Just bring them if you want a copy to refer to, and we will discuss them in class.

R34: Slides on problematic interactions between pharmaceutical companies and health care providers

**Readings on the “soft-law” approach to managing fraud and corruption**

R36: New York Times, “Gimme an Rx! Cheerleaders Pep Up Drug Sales”

R37: PhRMA Code on Interactions with Health Care Providers

R38: Questions on the PhRMA Code – We’ll work these in class, no need to look at them ahead of class.

Question to discuss in class: How much faith do you have in the “soft law” approach?

**Intro to the “hard-law” approach to corruption that we’ll be studying in detail**

R39: Fraud and Abuse Overview – just bring this with you. We will mention it to orient you to the “hard law” approach to corruption and fraud in health care. This will be a useful thing to bring to class for the next couple of weeks as we drill down into the topics on this outline/overview.

**March 20: Intro to False Claims Act**

 See assignment list in R40 (It lists your assigned readings)

 Readings and things to bring to class are at R39, R41, R42, R43 on Canvas

**March 26: False Claims Act, cont’d + Intro to Antikickback Statute**

 See assignment list in R44

 Readings and things to bring to class are at R39, R45, R46, R 47 on Canvas

**March 27: Anti-kickback Statute, cont’d**

 See assignment list in R48

 Readings and things to bring to class are at R39, R49, R50 on Canvas

**April 2: Stark Law (which is different from the Starks case!)**

 See assignments in R51

 Readings and things to bring to class are at R39, R52

**Topic: Privacy and Human Subject Protections**

**April 3: Overview of Data Privacy Generally (in Health Care and in Society)**

 See assignments in R53

 Reading: Skim R54 and bring the homework “thought piece” described in R53.

**April 9: How Medical Data Privacy Differs from Data Privacy Generally**

 See assignments in R55

 Readings and things to bring to class: Read R56, R57, bring R58

**April 10: Activities that Use Data; Intro to Human Subject Protections/Common Rule**

 See assignments in R59

 Readings and things to bring to class: Read R60, Scan R61, Bring 62, 63, 64

**April 16: Getting Deeper into the HIPAA Privacy Rule**

 See assignments in R65

 Readings and things to bring to class: Read highlighted passages in R66, R66a.

 **Bring R67, R68.** We will start discussing these problems, so look at them ahead of class to see which ones you might like

 to work on.

**April 17: Simulated real-world problem solving, cont’d**

 **R67, R68:** practical problem-solving exercises. Look at these problems before class and choose at least a couple to try to work before class.

 **We will discuss the problems in class and, if necessary, we can also schedule a zoom problem-solving/review session to help you get ready for the Final.**

***Continue to resources and course policies, next page*Resources and Course Policies**

**Important information** about UF Levin College of Law policies, including compliance with the UF Honor Code, Grading, Accommodations, Class Recordings, and Course Evaluations can be found at this link:  <https://ufl.instructure.com/courses/427635/files/74674656?wrap=1>

**You should take time to read this information. Do not put it off!**

**Health and wellness:** Law school can be a little daunting at times, and I am always happy to act as a sounding board on strategies to make it feel less stressful. If you or a friend is in distress, there are also other resources available on our campus:

* + *U Matter, We Care*: If you or someone you know is in distress, please contact umatter@ufl.edu, 352-392-1575, or visit the website at <https://umatter.ufl.edu/> for more information.

* + *Counseling and Wellness Center*: Visit the Counseling and Wellness Center website at <https://counseling.ufl.edu/> or call 352-392-1575 for information on crisis services as well as noncrisis services.

* + *Student Health Care Center*: Call 352-392-1161 for 24/7 information to help you find the care you need, or visit the website at <https://shcc.ufl.edu/>.

* + *University Police Department*: visit the website at https://police.ufl.edu/or call 352-392-1111 (or 9-1-1 for emergencies).

* + *UF Health Shands Emergency Room / Trauma Center:* For immediate medical care call 352-733-0111 or go to the emergency room at 1515 SW Archer Road, Gainesville, FL 32608; website at <https://ufhealth.org/locations/uf-health-shands-emergency-room-trauma-center>.
	+ Any student who has difficulty accessing sufficient food or lacks a safe place to live is encouraged to contact the Office of Student Affairs. If you are comfortable doing so, you may also notify me so that I assist you in locating further resources on campus.

**Other helpful resources:** E-learning center technical support, 352-392-4357 (select option 2).

**Conduct of classes**

**Naming and pronominal preferences:** I go by “Professor Evans” or “Barbara” and I use she/her/hers as my pronouns, although it won’t upset me if you use something else. I care about making sure I use your preferred name and pronouns, too. Please feel free to reach out to me in person, by phone, via text message, or by e-mail to make sure I know your preferences. Thereafter, if I ever fail to get it right, please kindly attribute it to defects of memory, and never feel awkward about correcting me gently in front of other people if I make a mistake.

You may also change your “Display Name” in Canvas. Canvas uses the "Display Name" as set in myUFL. The Display Name is what you want people to see in the UF Directory, such as "Ally" instead of "Allison." To update your display name, go to one.ufl.edu, click on the dropdown at the top right, and select "Directory Profile." Click "Edit" on the right of the name panel, uncheck "Use my legal name" under "Display Name," update how you wish your name to be displayed, and click "Submit" at the bottom. This change may take up to 24 hours to appear in Canvas. This does not change your legal name for official UF records.

**Recommendations for supplemental reading:** Students often ask me to recommend supplemental readings. Whether to use supplemental books is largely a matter of individual preference and study habits. Everything you need to know to do well in this class is in the Syllabus and in our class discussions. I don’t really have any recommendations, but if there is a particular topic you would like to delve into further, ask me and I’ll try to help you identify some useful resources.

**Contacting me with questions:** Never feel hesitant about e-mailing me, phoning me, texting me, or visiting office hours with a question if you have made a good-faith effort to understand something and it still is not clear. Please make sure to identify yourself if you text. It’s good to struggle a bit with new ideas and try to master them oneself, because the ability to read carefully and reason things out is a key skill one needs as a lawyer. However, if something just is not clear after a reasonable effort, you need to get it cleared up as soon as possible. Your knowledge of health law builds cumulatively. Things that are not clear early on can make the later phases of the course harder. It’s better to get things cleared up promptly if something just isn’t making sense. Don’t wait till the end of the semester to seek help.

**Course Requirements**

**Preparation:** It is anticipated that you will spend approximately 2 hours out of class reading and/or preparing for in-class assignments for every 1 hour in class.

**Class participation and attendance:** Attendance will be taken at each class meeting. Students are allowed two absences during the course of the semester. Students are responsible for ensuring that they are not recorded as absent if they come in late. A student who fails to meet the attendance requirement will be dropped from the course. The law school's policy on attendance can be found [here](https://www.law.ufl.edu/life-at-uf-law/office-of-student-affairs/current-students/uf-law-student-handbook-and-academic-policies).

Attendance in class is required by both the ABA and the Law School. If you miss more than four classes, your grade for the semester may be adversely affected. If you have a legitimate reason for missing class, you should contact me before or soon after class ends for your absence to be excused.

It is your responsibility to locate and initial the sign-in sheet for each class session. I will “call the roll” for the first couple of classes, while I learn your name. Thereafter, you are responsible for signing in. It will be considered a violation of the course rules and the Honor Code to falsely indicate that you were present in class, or to assist a classmate in such misrepresentation.

Punctuality shows respect for your colleagues and professors and is part of the professionalism expected of you as future lawyers. Please arrive at school early enough to allow yourself enough time to be in your seat ready to begin. Any student not in class within the first fifteen minutes of class (or leaving more than fifteen minutes early) is not permitted to sign the attendance sheet.

The best thing to do, if you know you are going to miss a class, is to ask a fellow student for notes. Student notes often are the best record of the give and take of questions and answers that actually took place during class. However, I also will be glad to discuss questions with you if you have been ill and need to go over any concepts that are still not clear.

**Lateness:**  Notwithstanding the prior rules, I understand that lateness sometimes happens despite students’ best efforts. Never feel embarrassed to join my class because you are slightly late. You’ve paid for the class, and I want you to get the benefit of any portion of it you are able to attend. However, you must be considerate of your fellow students if you are arriving late. When arriving late, sit in a free seat closest to the door to avoid disturbing other students, but maintain social distancing if required. Also, please don’t slam the door when you come in and make sure the door is closed behind you.

**What to do if circumstances require you to exit a class while it is in session:** From time to time in life, we all have a sudden illness or other emergency that requires us to enter or leave a class while it is in session. If this should happen to you, simply enter or leave as quietly and unobtrusively as you can, observing all social distancing requirements to protect others. Obviously, it is understood that you will do this only when there is a pressing need to do so.

**What good class participation means:** One of the goals of this class is to teach you lawyerly communication skills. It is surprising but true that the most important communication skill for lawyers is not talking and saying clever things, but listening and getting a sense of what other people think.

If you have previously asked to be recognized twice in a single class, I am unlikely to call on you again until all other persons in the class have had the opportunity to share their views. In that situation, do not continue to hold your hand up for a long time; it will just get tired. This is mainly done for your own learning. Whenever one is waiting to speak, one becomes completely absorbed with planning one’s own remarks and loses the opportunity to hear what other people have to say. Beware of being absorbed in your own thoughts, when you could be listening to what other people have to say.

Also, it is not the case that talking a lot leads to a higher class participation credit or makes you look wiser. Sometimes, a few well-chosen, well-prepared words are the most impressive. I particularly like it when students listen to one another’s remarks and respond to them, either to amplify or debate them in a tactful, well-reasoned manner.

Be aware of any implicit biases or positions of privilege that you may enjoy and regulate your participation in a way that ensures everybody has an opportunity to express their views and have them heard with respect.

**Practice examinations:** I do not give out old exams as practice exams. But we will work many class exercises and practice essay problems in class, so you will be well-prepared for the exams in this course.

**Final examination:**  Other than any adjustments for class preparation and participation (see above), the course grade will be based 40% on the Midterm and 60% on the Final Exam, as described in the Syllabus. The exam will be based on the assigned (required) readings and materials and topics discussed in class. More on the examination format will be discussed in class, or in general policies announced to the law school community, as the semester progresses.

The law school policy on exam delays and accommodations can be found [here](https://www.law.ufl.edu/life-at-uf-law/office-of-student-affairs/current-students/forms-applications/exam-delays-accommodations-form).

# Reading assignments/ Supplements: The Syllabus lists the assigned readings and other materials we will be covering. We will be proceeding straight through the Syllabus in the exact order it shows the readings. The pace at which we move through the materials may vary if I detect a need to slow down or speed up to ensure student mastery of the materials. Therefore, the dates shown on the Syllabus are indicative. I will announce specific assignments for the coming class periods at the start or end of each class or electronically via Canvas announcements. If you are unable to attend class for any reason, you are responsible for finding out what your assignments are.

**Problem sets**: Throughout the course we will be working problem sets. These are strictly learning exercises; they are not graded. The purpose of the problem sets is to help develop your analytical skills and learn how to apply the sometimes-theoretical course principles to specific fact situations. Also, the problem sets are intended to give you a taste of the types of questions you might see on the exams and in real health law practice.

**Cell phones, pagers, computers**: Please make every effort to remember to disable the ringer on your cell phone and to silence any other device you have that makes noise. I understand why carrying these devices in class is necessary. Computers in class are to be used exclusively for taking notes or viewing documents directly relevant to what is then going on in the classroom, and not for otherwise distracting you or your classmates. Sanctions for violating these rules are at my complete discretion.

**Class Recording Policy:** The Office of Student Affairs will continue to record all classes via Mediasite in case students must miss class for health reasons. The Office of Student Affairs will determine when students may have access to these recordings, and the recordings will be password protected. These recordings will be retained only for a short period of time and it is the student’s responsibility to contact the Office of Student Affairs as soon as possible after an absence. As a general matter, I am happy to make the class recordings available for anyone in the class to use for review purposes or to clarify issues discussed in class that you would like to go through again.

Under Florida law, students are allowed to record video or audio of class lectures. However, the purposes for which these recordings may be used are strictly controlled.  The only allowable purposes are (1) for personal educational use, (2) in connection with a complaint to the university, or (3) as evidence in, or in preparation for, a criminal or civil proceeding.  All other purposes are prohibited.  Specifically, students may not publish recorded lectures without the written consent of the instructor.

For this purpose, a “class lecture” is an educational presentation intended to inform or teach enrolled students about a particular subject, including any instructor-led discussions that form part of the presentation, and delivered by any instructor hired or appointed by the University, or by a guest instructor, as part of a University of Florida course. A class lecture **does not**include lab sessions, student presentations, clinical presentations such as patient history, academic exercises involving solely student participation, assessments (quizzes, tests, exams), field trips, private conversations between students in the class or between a student and the faculty or lecturer during a class session.

Publication without permission of the instructor is prohibited. To “publish” means to share, transmit, circulate, distribute, or provide access to a recording, regardless of format or medium, to another person (or persons), including but not limited to another student within the same class section. Additionally, a recording, or transcript of a recording, is considered published if it is posted on or uploaded to, in whole or in part, any media platform, including but not limited to social media, book, magazine, newspaper, leaflet, or third party note/tutoring services. A student who publishes a recording without written consent may be subject to a civil cause of action instituted by a person injured by the publication and/or discipline under UF Regulation 4.040 Student Honor Code and Student Conduct Code.

Also be aware that classes may be recorded by the Law School for the benefit of any students who need to be quarantined or otherwise miss class. By taking the class, you consent to any recording that proves necessary as part of these class-recording policies.

**Informal feedback for me:** My goal is to help you learn health law as thoroughly and enjoyably as possible. I welcome any comment or suggestion you may have regarding teaching style, topic coverage, class presentation, ways to make the class sessions more useful for you, or any other issue. I may not always implement every suggestion that is offered, but I will certainly give it careful consideration, and I would never be offended by any good-faith suggestion on how to make this class more engaging and productive for you. If something isn’t working for you, then let me know. Please feel free to provide me with any comments during the semester that you think will improve the overall learning experience.

**Formal course evaluations**: Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Also,I find this feedback extremely useful when planning future offerings of the class, so I’m very grateful for the time you take to fill in the GatorEvals. Students will be notified when the evaluation period opens and may complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or https://ufl.bluera.com/ufl/.