

## **HEALTH INDUSTRY BASICS**

**Fall, 2017**

**21446 – 5359 – Evans - 21446**

**Professor(s): Barbara Evans (FACULTY)**

**Credits: 3**

**Course Areas: Health Law**

**Time: 1:00-2:30pm MW, Room: BLB 209**

**SYLLABUS (Version 8-14-2017) COURSE POLICIES (see p. 10)**

**Grading:** an in-class, open book/open notes 70-minute-long midterm that counts for 50% of your grade, and a take-home final (which you check out from the library during the finals period on a day of your choosing) that counts for the other 50%. The midterm will be held on a date, during weeks 6-8 of the semester, to be chosen in consultation with the class. Since it is a graded assignment, students with bona fide conflicts or illness can work with Office for Student Services to reschedule, just as you could do with a final exam.

**Professor Barbara Evans**

**Office BLB 214**

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**Office Hours:** to be determined after classes begin.

You also may contact me by e-mail at any time to set up a time to meet.

**Message from the University:** Counseling and Psychological Services (CAPS) can help students who are having difficulties managing stress, adjusting to the demands of a professional program, or feeling sad and hopeless. You can reach CAPS ([www.uh.edu/caps](http://www.uh.edu/caps)) by calling 713-743-5454 during and after business hours for routine appointments or if you or someone you know is in crisis. No appointment is necessary for the “Let's Talk” program, a drop-in consultation service at convenient locations and hours around campus.  
[http://www.uh.edu/caps/outreach/lets\\_talk.html](http://www.uh.edu/caps/outreach/lets_talk.html)

**Course description:** This core health law course is an introductory tour of Texas/federal laws governing health-sector businesses, which together account for 18% U.S. Gross Domestic Product. The course covers traditional 20th-century institutions such as hospitals, but the main focus is on the expanding array of new players that supply innovative products and services (clinical laboratories; biobanks; academic medical centers, which conduct research as well as providing patient care; contract research organizations; health data exchanges; and management and informational services). 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.

This year's course will include visits from, and opportunities for students to have close interactions with, practicing attorneys and health administrators who work in major area academic medical centers.

The 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 era of big data and 21st-century genomic and "informational" medicine. **No prerequisites required other than completion of 1L courses.**

## **COURSE MATERIALS**

1. Clayton M. Christensen, *The Innovator's Prescription: A Disruptive Solution of Health Care* (McGraw Hill) – as of 3/21/2017, this book is available in hard cover for under \$21.00 with a kindle edition under \$13.00
2. This course also uses UH's Electronic Blackboard, where I will post most your additional readings. If you have not yet used the Electronic Blackboard, it is really easy. Sometimes it is balky if you use Internet Explorer and works better through other browsers like Firefox:
  - Go to Access UH: <https://accessuh.uh.edu/login.php>
  - On the credentials page where you log in, use the same name you use to log into UH emails. Put just the short name e.g. "msmith" and not "msmith@central.uh.edu" and also put your password and click to log in.
  - On the next page, there are icons. Choose the icon for Blackboard Learn 9.
  - Blackboard already knows which classes you're in, so it should list the blackboard for Health Industry Basics as one of your options. That's the one you want.
  - When you're finished, look for the "off" symbol (a circle with a vertical line) in the upper right corner and logout.

The Blackboard will include readings from several sources, including:

- THE AMERICAN HEALTH LAWYERS ASSOCIATION HEALTH LAW PRACTICE GUIDE (Thomson-West, 2013) Syllabus abbreviation: **HTHLPG** (*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
- TEXAS BOARD OF LEGAL SPECIALIZATION, SUGGESTED STUDY MATERIALS FOR PERSONS PREPARING TO BECOME BOARD CERTIFIED HEALTH LAWYERS IN THE STATE OF TEXAS Syllabus abbreviation: **TBLS** (*PDF files to be provided to students as supplements*). These materials consist of important state and federal statutes, regulations, and cases that the State Bar of Texas regards as foundational to the practice of Health Law in our state.

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

## **READING LIST**

### **I. INTRODUCTORY MATTERS**

#### **First Day Assignments**

**In your Christenson book, read Introduction**, SKIM pages xv - xli (stop at "Changes in Medical Education"). Then, focus on the attached Atul Gawande article (I've posted it as R1 in the Blackboard or you can access it via this link). Note: just skim the Christenson material, it's too much to read closely.

**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)

Write one page summarizing your views on how the concepts in Christenson may be relevant to solving the problem in Gawande's article and what you would do to reduce healthcare overutilization. Come to class ready to discuss.

#### **Supplements for use during in-class discussion: *no need to look at these before class***

- There are more than 70,000 attorneys licensed to practice in Texas. Only 7,000 are Board Certified. At present, the Texas Board of Legal Specialization directory lists only about 60 attorneys board certified in Health Law. *See* <http://www.tbls.org/Directory/Attorney.aspx> (searching on the Specialty Area "Health Law")
- The process for board certification: <http://www.tbls.org/Cert/AttyGetStarted.aspx>
- Topics required for Health Law certification: <http://content.tbls.org/pdf/attexmh.pdf>
- In class, we will discuss how to gain access to Institute of Medicine materials. As an example, we will look at the Institute of Medicine's recent Best Care at Lower Cost report: [http://nationalacademies.org/hmd/reports/2012/best-care-at-lower-cost-the-path-to-continuously-learning-health-care-in-america.aspx?\\_ga=2.74668242.1737098089.1502751007-990034784.1497022755](http://nationalacademies.org/hmd/reports/2012/best-care-at-lower-cost-the-path-to-continuously-learning-health-care-in-america.aspx?_ga=2.74668242.1737098089.1502751007-990034784.1497022755)

### **Class II: Introduction to Players in the Health Care Industry**

#### **Main topics:**

1. Who are the main players that provide healthcare and how is healthcare financed?
2. The basic tension between cost containment and quality of care

Note: The HTHLPG readings below are posted on the Blackboard for convenience, but just so you know, you can access them by logging into WestlawNext first, then minimizing WestlawNext on your screen so that it is running in the background, and then opening this document and clicking on the links below.

## **R2 – Intro A-B-C Providers, Private Payers, Medicare**

- Intro-A      AHLA HLHLPG on Providers  
What is health law? § 1:1. [Generally](#)  
Current trends in the Health Care Industry § 1:2. [Generally](#)  
Licensure/Credentialing § 1:8. [Generally](#)  
§ 1:9. [State approval to provide health care services](#)  
§ 1:10. [Federal oversight of professional credentialing and disciplinary activity](#)  
§ 1:11. [Accreditation and certification](#)
- Intro-B      AHLIA HLHLPG on Private Payers  
§ 1:16. [Third-party payment arrangements](#)  
§ 18:1. [Blue Cross](#)  
§ 18:2. [Blue Shield](#)  
§ 18:3. [More recent developments](#)  
§ 18:4. [Generally](#)  
§ 18:5. [Early efforts at cost containment](#)  
§ 18:6. [The advent of managed care](#)  
§ 18:7. [Countervailing forces to cost containment](#)  
§ 18:8. [Third-party administrators](#)
- Intro-C      AHLA HLHLPG Medicare  
§ 20:1. [Introduction](#)  
§ 20:2. [Program structure](#)  
§ 20:3. [Basic eligibility](#)

## **R3 – Intro-D Wickline v. State-excerpts**

- Intro-D      Wickline v. State (California)

## **II. RELATIONSHIPS BETWEEN PHYSICIANS AND HOSPITALS**

**Main topics:** The traditional relationship between healthcare professionals and healthcare institutions: corporate practice of medicine doctrine, medical staffing issues and institutional oversight of physician practice.

## **IV. The Corporate Practice of Medicine Doctrine**

### Readings

- R4 – CPM-1 Chase-Lubitz 40 Vanderbilt 445 1987 Corporate Practice of Medicine**

Jeffrey F. Chase-Lubitz, *The Corporate Practice of Medicine Doctrine: An Anachronism in the Modern Health Care Industry*, 40 Vand. L. Rev. 445 (1987) *excerpts*

**R5 – CPM-2 BerlinvSarahBushLincolnHealthCenter-excerpts**

*Berlin v. Sarah Bush Lincoln Health Center* - This is an Illinois case indicative of the modern trend followed in a lot of U.S. states

**R6 – CPM-3 FlynnBrosvFirst MedicalAssociates-excerpts**

*Flynn Bros v. First Medical Associates*, 715 S.W.2d 782 (Tex. App. 1986)

**Supplements for use during in-class discussion**

No need to read before class - Some of these are voluminous and I do not intend for you to read them ahead of time:

**R7 – CPM Sup1** How are hospitals formed in Texas

**R8 – CPM-Sup2** VTCA Tex Health and Safety Code 311.081-.083

Tex. Health & Safety Code 311.081-083 (formerly 311.061-013, as amended by SB 894 and SB 1093)

**R9 – CPM-Sup3** Tex. Occ. Code, Ch. 162

**R10 – CPM-Sup4** Link to Heard Article on Changes to TX CPM Doctrine  
David Heard, *Changes to the Corporate Practice of Medicine Doctrine*, Dallas Bar Association,

**CPM Review:** This class will be a combination of review, problem solving, and laying foundation for later material. We will complete discussion of the CPM problem distributed in the previous class. We will review R2-Intro A-B-C to highlight takeaway points. We will finish touring the key statutes and concepts in supplements R7-R10.

**Physician - Hospital Relations: Basic Medical Staff Issues and Institutional Oversight of Physician Practice**

**Readings: Basic Hospital Liability for Torts by Physicians**

**R11 – LIAB-1a Texas Medical Association Summary of Chapter 74**

Key aspects of Texas' medical liability framework

**R12 – LIAB-1b Painter – Chap 74 - The Malpractice Minefield**

**R13 – LIAB-2 Adamski v TacomaGeneralHospital-excerpts**

*Adamski v. Tacoma General Hospital* 579 P. 2d. 970 (Wash Ct. App. 1978)

**Supplement:** Review of Theories for Holding Hospitals Liable for a Physician's Tort

**R14 – LIAB-3 Baptist Memorial Hospital v Sampson-excerpts**  
Baptist Memorial Hosp. System V. Sampson, 969 S.W.2d 945  
(Tex 1998)

**R15 – LIAB-4 St. Joseph Hosp v. Wolff**  
St. Joseph Hosp. v. Wolff, 94 S.W.3d 513 (Tex. 2002)  
(This is a hard case, but TBLS regards this case as “core competency” material for Texas Health Lawyers, so it is good to know. Just give it a good-faith reading but don’t get hung up in it, and we’ll unpack it in class).

**Christensen reading (to be arranged)**

### **Credentialing of Staff and Liabilities Related to Credentialing**

**R16 – MedStaff-1 Basics of Physician-Hospital Relationship**  
AHLA HLHLP §§ 2.1 - 2.7, 2.12, 2.27 (ACOs)  
[§ 2:1. Relationship overview](#)  
[§ 2:2. Historical background](#)  
[§ 2:3. What are medical staff bylaws?](#)  
[§ 2:4. Generally](#)  
[§ 2:5. Medicare conditions of participation](#)  
[§ 2:6. Accreditation requirements](#)  
[§ 2:7. --The Joint Commission](#)  
[§ 2:12. State Licensure Laws](#)  
[§ 2:27. Healthcare entity/physician integration issues](#)

**R17 – MedStaff-2 EwerCCMS Orientation slides – 2012**

**R18 – MedStaff3 Lawrence R Poliner, MD; v. Texas Health Systems 5<sup>th</sup> circuit appeal** 537 F.3d 368 (5<sup>th</sup> Cir. 2008)

**R19 – MedStaff Johnson v Misericordia excerpts**

**R23 – Medstaff 8 DallanJudicial Review of Credentialing**

Craig W. Dallan, *Understanding Judicial Review of Hospitals’ Physician Credentialing and Peer Review Decisions*, 73 Temp. L. Rev. 597 (2000).

Start reading at internal page \*598 (on page 4 of the PDF) and continue through \*636 (Page 14). It is OK to skip the discussion of hospital liability. Then resume reading on page \*630 (PDF page 15) with section “2. Nonreview” and continue reading to \*643 (PDF page 20), stopping at “2. Defining a Contract”

**R20 – Medstaff 5 St Lukes v Agbor-Read majority opinion p 2-6 only**  
**Class handout - Are bylaws a contract in Texas?**

These materials are supplements that may be mentioned in class:

R21 – Medstaff 6 Roe v Walls  
R22 – Medstaff 7 Moreno v Quintana  
R24 – Medstaff 9 Ching v Methodist Children’s Hosp

**R25 – Medstaff 10 HTHLPG s2-10 HCQIA**

AHLA HTHLPG § 2.10 (*selected portions*)

§ 2:10. Health Care Quality Improvement Act of 1986

**R25-Supp-1 Sec. 160010 Immunity from Civil Liability**

Tex. Med. Practice Act (Tex. Occ. Code §§ 160.001 - .015)

**R25-Supp-2 Federal HCQIA (42 USC Sec. 11101-11152)**

**R-26 – Medstaff 11 NPDB Guidebook (Chs.A-E)**

**The Role of Clinical Practice Guidelines**

**R27 – Medstaff 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

Discussion of student thought papers concerning the impact of conflicts of interest on the development and use of Clinical Practice Guidelines

**R28 – Barry Furrow Regulation Patient Safety**

Discuss provisions of the ACA that promote patient safety

**III. ACADEMIC MEDICAL CENTERS AND RESEARCH OVERSIGHT**

**Protecting Human Subjects in Biomedical Research**

The following materials are very important and should be studied carefully:

**R33: Gelsinger Case Summary**

**R34: Common Rule Excerpts**

**Human Subject Protection Intro Slides—posted on blackboard**

**Text Handout Human Subject Protections – posted on blackboard**

The following articles are important because they reflect an emerging and still controversial view, which is at odds with the current Common Rule, that people may have a bounded duty to allow their data to be used in socially beneficial research and public health activities:

**R34a: Articles on Learning Healthcare System**

Problems we worked in class—very important to understand these:

**Problems: QI vs. Research—posted on the Blackboard**

**Problems: Public Health Practice vs. Research – posted on the Blackboards**

**R37: In class practice problem**

SUPPLEMENTS: These were not assigned. They are useful background to have in your files if, in the future, you ever have to work QI vs. Research and Public Health Practice v. Research problems in your law practice. I recommend downloading and keeping these, as the Hodge Gostin report is out of print and hard to find now. It is excellent.

**R34e: Hodge Gostin – Public Health vs. Research**

**R38: OHRP Guidance Engagement in Research**

**R39: More OHRP Guidance on Nonengagement in Research**

**R40: Solution to the R37 in class practice problem.**

Materials on HIPAA: You need to understand these and be able to explain how HIPAA's handling of jurisdiction, treatment/QI/public health, research waivers, and other categories of use differs from the Common Rule. Also understand the basic obligations covered entities have to get authorizations, protect information, etc.

**R34b: Ewer HIPAA Slideset**

**R34c: Ewer HIPAA Algorithm Slide**

**R34d: HIPAA Privacy Rule Excerpts**

**Link to Office for Civil Rights HIPAA Covered Entity Decision Tool—emailed to you.**

### **Research Integrity Readings**

After HIPAA, we will go back and cover research integrity. The following materials are the core stuff you need to master:

**R29: Office for Research Integrity (ORI) Intro Readings**

**Research Integrity Notes and Problems—posted on Blackboard**

SUPPLEMENT, not assigned: The following is a supplement, which you may wish to download and keep. It provides some empirical data of the procedural protections that institutions actually provide. They *must* provide the protections specified in the regulation 42 CFR 93, but that leaves a lot of room for variation as to the details, so it's good to see how institutions handle things, in case you ever need to design a research integrity procedure for a client.

**R30: ORI – Institutional Practices**

SUPPLEMENT, not assigned: The following is useful as an example of how seriously bad things can get when a researcher violates the regulations, and also it shows how detailed the internal institutional investigation can be, when an institution detects a problem with one of its researchers. The institution in this case avoided a lot of



problems for itself by taking the problem seriously and doing a thorough internal investigation.

**R31: Supp: Poehlman Settlement Agreement**

SUPPLEMENT: The AHLA write-up in R29 tells you just about all you need to know, but it can be useful to have the regulation and the preamble, so that you can look up exact definitions. But you do not need to pore over this regulation.

**R32: Supp: ORI 42 CFR 93**

**Review and Practice on Human Subject Protections and Privacy Topics**

**R35: OHRP Letter on Coercion**

**R35a: OHRP Guidance, Evans notes re Coercion**

**R36: Example OHRP Oklahoma Letter**

**R39a Health Aff-2014-Cohen-1139-47.pdf**

**R39b: J Halamka Early Experiences Article**

**R39c - PCAST Report (2014) Read Pages 33-45 Only**

**IV. CLINICAL LABORATORY REGULATION AND RIGHTS OF PATIENTS AND RESEARCH SUBJECTS**

**R41: SUPP CLIA: Yost-Yamamoto CLIA 101**

**R42: CLIA Regulation Excerpts**

**R43: GAO Report on CLIA Oversight**

**R43a: CLIA Return of Results Slides**

**R44: Incidental Findings: JP Evans Article from Genetics in Medicine**

**R44a: Burke et al article Incidental Findings: Research vs. Clinical Practice**

**R45: ACMG Guidelines on Incidental Findings**

**R45a: Impact of new CLIA-HIPAA Access Provisions**

**R45b: 45 CFR sec. 164.524 Individual Access Rights**

**R45c: HHS Office for Civil Rights Guidance on Rights of Access**

**R45d: Problems – Individual Access Rights**

**R46: CLIA Patient Access Rights**

## **COURSE POLICIES**

**Attendance:** You are expected to attend class sessions and to arrive on time. If circumstances force you to enter the classroom late, please do not let the door slam and please take a free seat near the door to avoid distracting your classmates to go to your regular seat. You must comply with the Law Center's overall attendance policy, which allows no more than five absences in a 14-week, twice-a-week course. Your compliance with that policy is a requirement that professors have no discretion to alter or waive. However, I will work with you to help ensure continuity of your learning if you should be forced to miss a class or two for a *bona fide* work-related, health, or other pressing necessity.

You are not required to contact me to explain your first two absences from class, but I am always glad to hear from you because I am concerned to know if you are busy or swamped at work and I will save you copies of any class handouts if you are away.

**Class participation:** This is not a good class to take if you want to sit back and passively monitor the proceedings. I enjoy getting to know all my students and I will quickly learn your name; thereafter, I shall call on everybody all the time. My aim in calling on you is not to intimidate or embarrass you, but simply to make sure we involve everybody in a lively debate. At my discretion, a student's final grade may be adjusted upward or downward by one "notch" (e.g., from B+ to A-, or from B- to C+) in recognition of classroom contributions or lack thereof. And remember: A big part of participation is listening and thinking about others' points of view.

**Cell phones/pagers:** Of course you should set your electronic devices to silent mode! I confess that the only time I ever had a cell phone go off in my classroom, it was my own cell phone. Thus I appreciate how hard it can be to remember this rule, but please try.

**Use of computers:** I support the use of computers in the classroom. Unless otherwise announced in class, you may use your computers to take notes and look up statutes, regulations, and administrative materials that we are discussing. During class, I would like to see your computers being used only for course-related purposes. Non-course-related use of e-mail and the Internet is strongly discouraged. The point where I draw the line is if you use your computer or other communication devices in ways that become annoying or distracting to fellow students. Sanctions for violating these provisions can include adjusting a student's final course grade downward or suspending a student's right to use a computer in this class, and such sanctions may be imposed without warning at my sole discretion.

**Recording class:** Please do not record class without my express permission. I like for class to be a safe environment where students feel free to speak their minds and explore speculative ideas without having to worry that their remarks are being memorialized.