

HEALTH INDUSTRY BASICS
LAW 5397-EVANS-25374—Fall, 2014
SYLLABUS (Version 8-21-2014)

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Office Hours: Thursday 5 – 6 and an additional time to be arranged after classes begin.
You also may contact me by e-mail at any time to set up a time to meet.

Course: 5397 Health Industry Basics: Providers-Innovators-Regulators - EVANS- 25374
Professor(s): Barbara Evans (FACULTY)
Credits: 3
Course Areas: Health Law
Time: 1:00p-2:30p MW
Location: 240 BLB

See Reading List and First Day's Assignment, starting on page 3

See Course Policies, starting on page 10

Course description: This new core health law course is an introductory tour of Texas/federal laws governing health-sector businesses that together account for 18% U.S. Gross Domestic Product, including traditional 20th-century institutions like hospitals and an expanding array of new players that supply innovative products (drugs, devices, diagnostics) and services (clinical laboratories, biobanks, contract research organizations, health data exchanges, management and informational services) to healthcare providers and—increasingly—directly to consumers. This course acquaints students with the core corporate client base for large-firm and in-house health lawyers; introduces major regulatory frameworks that struggle to safeguard consumers' rights vis-à-vis commercial health-sector enterprises; and identifies 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, JEROME H. GROSSMAN & JASON HWANG, *THE INNOVATOR'S PRESCRIPTION: A DISRUPTIVE SOLUTION FOR HEALTHCARE* (McGraw-Hill, 2008)
Syllabus abbreviation: **CGH**
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:
 - Go to the main UH web page: www.uh.edu
 - Look for the red box at upper right: "Login to AccessUH" and click there
 - 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

August 25, 2014 - First Day Assignments

In your Christenson book, read **Introduction**, pages xv - xli (stop at "Changes in Medical Education").

Quickly read the attached article (I've posted it as R1 in the Blackboard or you can access it via this link):

Atul Gawande, *The Cost Conundrum*, NEW YORKER, June 1, 2009,
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 59 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/attxmhe.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://www.iom.edu/reports/2012/best-care-at-lower-cost-the-path-to-continuously-learning-health-care-in-america.aspx>

August 27, 2014: 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 WicklinevState-excerpts

Intro-D Wickline v. State (California)

September 1, 2014: Labor Day Holiday

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.

September 3, 2014

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 BerlinSarahBushLincolnHealthCenter-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,

<http://www.dallasbar.org/content/changes-corporate-practice-medicine-doctrine>

September 8, 2014

Read: Christenson, Chapter 1, pages 1 – 30. This class will be a combination of review, problem solving, and laying foundation for later material.

- **Write a short 1 page thought piece** about the following concepts based on the Christenson reading and come to class prepared to discuss: What is the “job-to-be-done” that people want the healthcare system to do for them? Are there more than one “job”? Which aspects of healthcare fit into the “solution shop,” “value-adding process,” and “facilitated network business” models? Which of the things

you learned so far in the course seem to stand in the way of business model innovation?

In class, we will also do a bit of review as follows:

- 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).

September 10, 2014

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

September 15, 2014

R14 – LIAB-3 BaptistMemorialHospitalvSampson-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).

Christenson Reading: Chapter 3, page 73 – 105

Credentialing of Staff and Liabilities Related to Credentialing

R16 – MedStaff-1 Basics of Physician-Hospital Relationship

AHLA HLHLPG §§ 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 5th circuit appeal 537 F.3d 368 (5th Cir. 2008)

R19 – MedStaff Johnson v Misericordia excerpts

R23 – Medstaff 8 DallonJudicial Review of Credentialing

Craig W. Dallon, *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

Christenson, Chapter 2: The Technological Enablers of Disruption

Christenson, Chapter 5: Disruptive Solutions for the Care of Chronic Disease

Research Integrity Readings

R29: Office for Research Integrity (ORI) Intro Readings

R30: ORI – Institutional Practices

R31: Supp: Poehlman Settlement Agreement

R32: Supp: ORI 42 CFR 93

Protecting Human Subjects in Biomedical Research

R33: Human Subject Protections Intro

R34: Supp: Human subject protection regulation

R35: Example: OHRP Letter re coercion

R36: Example: Oklahoma OHRP Letter

R37: In-class practice problem

R38: OHRP Guidance – Engagement in Research

R39: More OHRP Guidance on nonengagement in Research

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**
- R44: Incidental Findings**
- R45: ACMG Guidelines on Incidental Findings**
- R46: CLIA Patient Access Rights**
- R47: Burke et al article: Clinical practice vs Research**

V: THE ROLES OF STATE AND FEDERAL LAW IN REGULATING PATIENT SAFETY

- R3: Review the Wickline case at R3**
- R48: Tex Civ Prac and Rem Code s 88.001**
- R49: Mills and Pautler ERISA Article**
- R50: ERISA Slides**
- R51: ERISA Preemption Questions**

VI. PROTECTING THE PRIVACY OF HEALTHCARE INFORMATION

- R52: HHS Office for Civil Rights – HIPAA Covered Entity Charts**
- R53: HIPAA Breach Resolutions**
- R54: HIPAA Privacy Rule Excerpts for in-class exercise on how to navigate the HIPAA Privacy Rule**
- R55: Data Ownership, Access, and the Critical Role of Data in 21st Century Biomedical Research and Patient Care**

VII. SELECTED TOPICS: HOT POLICY ISSUES

FDA's Draft Guidance on regulation of laboratory-developed tests is expected to be published by October. Depending on how that progresses, we may select that as our topic for this unit of the course.

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.

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 strongly 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 would get fierce is if you were using your computer or other communication devices in ways that were distracting your 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.

Examinations and grading:

Ungraded thought pieces. During the semester, there will be several times when I ask you to prepare a brief, one- or two-page "thought piece" reflecting on topics covered in

our readings and discussions. **These short papers will not be graded, so you should turn them in using your name rather than exam number.** These will be announced ahead of time and will be due on the date specified, with no late papers accepted. If you anticipate being away, you should make arrangements to turn in your thought pieces ahead of the specified due dates.

In-class midterm (30% of course grade). At an agreed date near the middle of the semester, *with clear prior notice*, I will administer a midterm covering approximately the first 1/3 of the course material, which will then not be covered again on the final. This will be an open-book, open-Internet, open-outline test lasting 75 minutes (i.e., it will be taken during a regular class meeting).

Take-home final exam (70% of course grade). The final exam will be an open-book, essay format, take-home exam that will pose one or more transactions-oriented problems or questions requiring analysis of regulatory policies covered during the semester. You may be asked to advise a hypothetical client on a proposed health industry transaction or on a hypothetical regulatory problem.