**HEALTHCARE FINANCING, ORGANIZATION & QUALITY**
**PROF. EVANS (LAW 6331-EVANS-23497—Spring, 2014)**
**SYLLABUS VERSION 1-13-2014**

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**Office Hours:**
**Th 5 - 6**
**and by appointment--email me to set up a time that works**

**CLASS TIME** MW 6-7:30 p.m. **FIRST DAY'S ASSIGNMENT IS ON PAGE 6 BELOW**

**COURSE OVERVIEW** This introductory course requires no prerequisites other than completion of the general 1L curriculum. This course is designed to avoid overlaps with the Law Center's other basic health law course (Health Law Survey). Students can take either or both of the basic health law courses and can take them in any order. This section of the course is scheduled to be taught one time only in Spring, 2014 in the evenings. The evening meeting time creates opportunities for visits by, and student interaction with, practitioners.

This section of *Healthcare Financing, Organization, and Quality* covers the same body of laws and regulations that this course traditionally has covered, but as its unifying theme, we will explore how these existing laws may pose barriers to fundamental cost- and biotechnology-driven restructuring of the healthcare industry. We will reflect on the following hypothesis: "Medicine is about to go through its biggest shakeup in history,"[1] but this restructuring may have little to do with the Affordable Care Act (also known as "Obamacare"). The recent debate about the Affordable Care Act "centered on medicine of the present rather than medicine of the future…. When viewed in the context of medicine of the present--current healthcare is ineffective, costly, and therefore impossible to extend to all citizens. The healthcare debate today is about rationing and who will be left out or poorly served."[2] Unnoticed in this debate is that the U.S. healthcare system is on the brink of an epochal cost- and biotechnology-driven restructuring which, by some accounts, will force every healthcare institution in America to rewrite its business plan during the next five years.

If you plan to practice in Texas, being practice-ready requires knowledge of Texas law. Under principles of federalism, much of the authority to regulate health case traditionally has resided with the States. The post-1960 overlay of major federal statutes has not displaced the role of the States, which continue to play crucial roles in overseeing the healthcare industry. This section of *Healthcare Financing, Organization, and Quality* is designed to acquaint students with relevant Texas statutes and case law, as well as covering major federal statutes and multistate trends.

This course provides a practice-oriented survey of key laws and regulations that one needs to know to work as a health law practitioner, as in-house counsel or as a compliance or risk management officer at healthcare institutions such as hospitals, academic medical centers, and labs or at an insurer or managed care organization. Because most major Fortune 500 U.S. corporations provide employer-sponsored health insurance through what is known as ERISA self-insured benefit plans, this course also addresses issues of interest to students aiming for jobs as in-house counsel at major industrial corporations outside the healthcare sector.

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1 Eric Topol, The Creative Destruction of Medicine vi (2012).
2 Leroy Hood, P4 Medicine, at http://phc.osumc.edu/2009/10/02/p4-medicine-dr-leroy-hood-on-digitalizing-and-personalizing-health-care/

## COURSE MATERIALS

The current estimated cost of purchasing books for this course is approximately $37.00 plus any applicable shipping costs.

1. ERIC TOPOL, THE CREATIVE DESTRUCTION OF MEDICINE (Basic Books, 2012)
   Syllabus abbreviation: **TOPOL**
   (*available now in paperback for approx. $14.00 or Kindle edition for approx.. $10.00*).

2. CLAYTON M. CHRISTENSEN, JEROME H. GROSSMAN & JASON HWANG, THE INNOVATOR'S PRESCRIPTION: A DISRUPTIVE SOLUTION FOR HEALTHCARE (McGraw-Hill, 2008)
   Syllabus abbreviation: **CGH**
   (*available now in hardcover for approx. $23.00 or in Kindle edition for approx $ 18.50*)

3. 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. The LAW PRACTICE GUIDE is now available to UH students through your Westlaw accounts. We will harness this resource to help you quickly master several of the crucial legal frameworks that affect how healthcare is financed, organized, and regulated to promote patient safety and quality of care.

4. 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.

## HOW THIS COURSE FITS WITH OTHER COURSES AT UHLC

The outline on the next page below lists core competencies that the Texas Board of Legal Specialization considered essential to the practice of health law. This course develops the competencies shown in BLUE. It does not duplicate coverage of topics covered in Prof. Roberts' Health Law Survey, Prof. Clark's Fraud and Abuse course, Prof. Buckles' general course in taxation of non-profit entities, or in a general healthcare transactions course. However, a brief summary of fraud and abuse and issues with hospital taxation and healthcare transactions is included for those who have not yet had those courses.

**TEXAS BOARD OF LEGAL SPECIALIZATION HEALTH LAW COMPETENCIES**

**Topics covered in Healthcare Finance, Organization, and Quality**

1. Licensing, Discipline, Credentialing, and Peer Review of Health Care Professionals
   a. Physicians and physician assistants
   b. Nurses, including advanced practice registered nurses
   c. Multi-disciplinary entities (e.g., clinical labs, academic medical centers)
2. Hospitals and other Health Care Entities
   a. Licensing and certification
   b. Accreditation
   c. Medical staff issues (including peer review processes)
   d. Compliance programs
   e. Operations and patient safety (other than basic patient care issues)
3. Patient Care Issues
   a. Patient rights, including consent to treatment and advance directives
   b. Confidentiality of patient information, including HIPAA and applicable Texas law, and electronic health records
   c. Hospital transfers and emergency services
   d. Mental health [covered in Prof. Winslade's mental health-related courses]
   e. Clinical research
   f. Abuse and neglect
   g. Theories of civil liability for services furnished to patients
      - Liability of physicians
      - Liability of institutions (hospitals, laboratories, nursing homes, etc.)
      - Liability of managed care providers
4. Financial Aspects of Health Care Services
   a. Managed care contracting, networks, and billing Medicare/Medicaid
   b. eligibility, reimbursement, and related issues Antitrust issues in
   c. IPAs (including clinical integration) and boycotts
   d. Corporate practice of medicine/physician practice structures and contracting
5. Health Care Transactional Issues
   a. Federal and Texas anti-kickback laws (summary coverage provided here)
   b. Federal and Texas restrictions on physician referrals to entities with which the financial relationship (including the federal "Stark" law) (summary coverage provided here)
   c. Acquisition and sale of health care entities (introductory coverage)
   d. Joint ventures (introductory coverage)
   e. Restrictive covenants (i.e., non-compete, non-solicit, non-hire, proprietary information)
   f. Tax-exempt issues
   g. Charity care

## COURSE POLICIES

**Attendance:** You are expected to attend class sessions and to arrive on time, although I understand the realities of evening rush-hour traffic in Houston and will show clemency as long as you make earnest efforts to get to class by 6:00 pm. If circumstances force you to enter the classroom late, ***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.

I also understand that many of you have day jobs that occasionally require business travel that is beyond your control. 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 an absolute 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 and then cram at the end just to get ready for the final. You will not be cloaked in anonymity in my classroom. 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. We will be discussing some very grave problems with the U.S. healthcare sector that have the potential to undermine our nation's economy if the next generation of lawyers does not design and implement better solutions than previous generations have done. Everybody in our classroom will be drawn into the conversation. 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. If a professor cannot make him- or herself more interesting than your computer screen, then the professor deserves inattention. 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.

**Examination 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 diagnostic quizzes (30% of course grade)**. At several points in the semester, ***with clear prior notice***, I will administer brief diagnostic quizzes on important substantive points covered in our assigned readings. The purpose of these short diagnostic quizzes is twofold: (1) to provide intermediate feedback during the semester on your mastery of essential course topics; and (2) to consolidate your knowledge of basic points of law and facts about the healthcare industry that will facilitate your analysis of the problems explored in this class. These short in-class diagnostic quizzes will be announced ahead of time and should not pose any difficulty if you are keeping up with your assigned readings. **They will be graded, so you will use your exam numbers for these.** After each quiz, we will go over the correct responses in class.

**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 healthcare transaction or on a health-industry restructuring proposal, identifying problematic aspects of the proposal based on laws we have studied in the class and developing proposed solutions to the problems you have identified.

**PROCEED TO COURSE OUTLINE ON PAGES 6 - 9**

**ALL READINGS AND STATUTORY SUPPLEMENTS WILL BE POSTED ON BLACKBOARD.**

**FOR STUDENTS WHO PREFER IT, A COMPREHENSIVE READING LIST WITH ACTIVE WESTLAW LINKS TO READINGS WILL BE PROVIDED TO STUDENTS REGISTERED IN THE CLASS.**

# COURSE OUTLINE

## INTRODUCTORY MATTERS

**DAY 1 ASSIGNMENT: January 13, 2014**

**Topol, The Creative Destruction of Medicine**

Skim Introduction (pages v - xi)

Skim: Chapter 1 (pages 3 - 18): skim quickly for main themes and trends, most of which you already are aware of

**Read: Chapter 2 (pp. 19 -32) read carefully**

**Atul Gawande**, *The Cost Conundrum*, NEW YORKER, June 1, 2009, www.newyorker.com/reporting/2009/06/01/090601fa_fact_gawande

**Day 1 Assignment:** Write a short (1 page, or up to 2 pages max) "thought piece" on the following topic. Bring it with you and turn it in at the start of class. This assignment will not be graded but turning it in is how I will mark you as "present" on the first day of class. Naturally, if you add the class after Day 1, this assignment will be due on the first day you are enrolled.

**Antibiotics became widely available after the mid-1940s. The rise of large hospitals in the last half of the 20th century coincided with the availability of effective antibiotics. Clustering large numbers of sick and immune-compromised people under one roof was feasible in part because antibiotics could manage the risk of intra-institutional disease transmission. U.H. pharmacologist Vincent Tam predicts that antibiotics will cease to work in the next 5 - 10 years, because widespread over- and misuse of antibiotics has favored the evolution of antibiotic resistant organisms. How may the end of "the antibiotic era" affect the future structure of the healthcare industry?**

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/attexmhe.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

**January 15, 2014: Introduction to 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

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|---|---|
| Intro-A | Overview of Healthcare Providers |
| Intro-B | Overview of Private Payers |
| Intro-C | Overview of Medicare |
| Intro-D | Wickline v. State (California |

**III. January 20, 2014: Holiday**

**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. **READINGS TO BE AVAILABLE VIA BLACKBOARD.**

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

This unit examines the Corporate Practice of Medicine doctrine, which restricts the ability of corporate entities to employ physicians. It introduces the original rationales for the doctrine, which many states have now abandoned. Then, we survey Texas case law preserving the doctrine but also examine Texas statutes that afford exceptions to the doctrine. This doctrine has had a profound influence on the medical staff relationships (the relationships between doctors and hospitals), which traditionally have neither been an employment or independent contract relationship but more in the nature of a license.

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

**Basic Hospital Liability for Torts by Physicians**

This unit introduces key aspects of Texas' statutory framework for medical liability, and then reviews multistate doctines under which a hospital can be liable for acts of physicians practicing at hospital facilities. Then, we will examine two cases that highlight differences between multistate and Texas doctrines.

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

This unit introduces medical staff relationships and the bylaws that govern physicians' relationships to hospitals. It looks at the process through which doctors become "credentialed" to practice at a hospital and the peer review processes hospitals use to oversee physicians' quality of care. It examines key state statutes relating to disputes that can arise in connection with credentialing and peer review, including disputes when the hospital denies privileges to work at the hospital, suits for negligent credentialing. Multistate and Texas doctrines will be compared.

**Peer review under the federal Health Care Quality Improvement Act**

This unit examines judicial review of hospitals' credentialing decisions and processes for overseeing the quality of physician care, focusing on immunities afforded under HCQIA and important Texas and Fifth Circuit decisions that affect the peer review process in Texas. Texas statutes affecting the peer review process also are introduced.

## REGULATORY APPROACHES TO PROTECT PATIENTS' RIGHTS

Patient Safety & Rights: Diagnosis and Prevention

1. The role of diagnostics and clinical laboratories in present and future health care
2. Certification and regulation of clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)
3. State laws concerning reporting of diagnostic test results
4. Proposed amendments to the CLIA regulations that affect reporting and patients' rights of access

Patient Safety & Rights: Treatment and Long-term Care

1. Difficulties defining and assessing the quality of care
   - Institute of Medicine's findings for health care generally
   - Institute of Medicines findings on quality metrics for cancer care
2. Readings from CMG on the three distinct roles of health care facilities: solution shops, value-added factories, and precision medicine
3. Clinical guidelines and comparative effectiveness initiatives, and why they have limited utility in major segments of the health care industry.
4. Major state and federal regulations addressing the quality of care; roles of state and federal regulators in overseeing quality of care
5. The role of private entities in defining and overseeing quality of care
   - Private accreditation bodies and deemed status
   - Private involvement in development of clinical guidelines

   Cases and commentary challenging the private role in health care governance
6. Provisions of the Affordable Care Act that aim to improve quality of care

The Blurring of Treatment and Research in 21st-century Health Care

1. The 21st-century "Learning Health Care System"
2. Federal protection of human research subjects under 45 C.F.R. pt. 46
3. Federal oversight of conflicts of interest and other forms of scientific misconduct
4. Texas' framework of protections for patients who become subjects of research

Medical Records and Privacy Protection

1. Patient protections under the HIPAA Privacy and Security Rules
2. Texas medical records law and medical privacy law

**RELATIONSHIPS BETWEEN PHYSICIANS AND PRIVATE PAYERS/MANAGED CARE ORGANIZATIONS/INTEGRATED HEALTHCARE STRUCTURES**

1. Basics of managed care contracts and physician incentives
2. Specific terms of managed care contracts that create risks for patients and physicians
3. Model terms and goals in negotiation of managed care contracts
4. The history and current status of state efforts to address risks for patients and physicians
5. The major Texas legislation to protect patients and physicians in relation to managed care

**THE BALANCE OF STATE AND FEDERAL REGULATORY AUTHORITY TO PROTECT PATIENT SAFETY**

1. Preemption under ERISA, which governs employer-sponsored health benefit plans
2. ERISA's dispute resolution framework and remedies
2. Preemption provisions of the HIPAA Privacy Rule
3. Preemption provisions of the HIPAA statute

**PROTECTION OF HEALTHCARE PAYERS**

1. Overview of governmental and private payers
2. Federal and Texas Anti-kickback Laws and Civil Monetary Penalty Laws
3. Federal and Texas Restrictions on Physician Referrals
4. Federal and Texas False Claims Act

**VISIONS FOR THE FUTURE OF THE HEALTH CARE SYSTEM**

1. Predictive, preventive, participatory medicine
2. Direct-to-consumer care
3. New models for care of chronic disease
4. Mobile health and telemedicine
5. Networked care models

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**STRUCTURE, FINANCING, AND GOVERNANCE ISSUES THAT POSE BARRIERS TO FUNDAMENTAL REFORM**

**PROVISIONS OF THE AFFORDABLE CARE ACT THAT PROMOTE STRUCTURAL REFORM**