HEALTH INDUSTRY BASICS: PROVIDERS-INNOVATORS-REGULATORS
Prof. Barbara Evans (LAW 5397-EVANS-25374—Fall, 2014)
Preliminary Syllabus 3-18-2014

CLASS TIME MW 1:00-2:30 p.m.

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Office Hours:
to be announced 8/2014
or by appointment--email me to set up a time that works

COURSE OVERVIEW 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.

PREREQUISITES: ***No prerequisites required other than completion of 1L courses***. This is one of three core health law courses that can be taken in any order by students wishing to focus on Health Law. This course also is suitable as an elective for students who do not intend to specialize in health law but who wish to become conversant with the basic business structure of the healthcare industry and to understand key legal and regulatory challenges facing commercial health-sector businesses.

COURSE MATERIALS
The current estimated cost of purchasing books for this course is approximately $23.00 plus any applicable shipping costs.

1. 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*)

2. 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 introduction to key federal laws governing the Health Industry. The LAW PRACTICE GUIDE is now available to UH students through your Westlaw accounts.

3. 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 posted to course Blackboard*).
   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.

ALL READINGS (OTHER THAN THOSE IN THE CHRISTENSEN BOOK) AND ALL STATUTORY SUPPLEMENTS WILL BE POSTED ON THE UH ELECTRONIC BLACKBOARD.

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.

COURSE OUTLINE

As this is a new course, a more detailed syllabus and reading list will be posted in August, 2014. The list below is provided to help clarify the major topics covered in this course.

Introduction to the modern commercial healthcare sector

- Post-1990s business models in healthcare: the shift from the 20th-century general hospital/solution shop model to value-added process models and facilitated patient network models in healthcare; the ongoing shift from curative (sickness-oriented) to prospective (prevention-oriented) medicine; the roles of big data and "informational" medicine in today's healthcare system.
- Basic licensure, accreditation, and state and federal of institutions that provide healthcare (hospitals, nursing homes, ambulatory surgical centers, managed care organizations (as

providers/arrangers for care) and certification/contracting with governmental and private payers.

- The role of clinical laboratories that provide genetic and other diagnostic testing services. Certification of clinical laboratories under CLIA ’88 (42 U.S.C. § 263a & 42 C.F.R. pt. 493); restructuring of the clinical laboratory industry in response to next-generation genomic sequencing.

- Research administration and compliance obligations of academic medical centers (i.e., hospitals that provide healthcare while also engaging in biomedical research and discovery) and multi-site research networks (regulation under 45 C.F.R. pt. 46 & 21 C.F.R. pts. 50, 56 (human subjects/biobanks); 42 C.F.R. pt. 93 (research integrity and quality of data to support evidence-based medicine); interactions with research organizations (CROs); proposed changes under the Common Rule ANPRM).

- Medical products manufacturers (pharmaceutical and medical device manufacturers). Pharma-provider interactions (conflicts of interest, fraud compliance, overreaching provisions in privately-sponsored research contracts).

- Medical records, health information exchanges, distributed data networks: compliance under state medical records law and Tex Occupations and Health & Safety Codes; HIPAA privacy and security rules; Federal Privacy Act.

- The private and governmental roles in clinical guideline development and clinical trial data sharing; IOM recommendations on clinical guideline development.

Basic institutional-provider relationships and oversight of the quality of care

- The corporate practice of medicine doctrine (national trends and Texas); liability of provider institutions; Texas doctrines on allocation of liabilities in multi-institutional settings.

- Scope-of-practice, credentialing, privileging, peer review, reporting obligations, and immunities (Federal HCQIA & PSQIA, Texas Health & Safety Code, Texas Occupation Code, common law)

- Liabilities of health-sector businesses: hospitals, research institutions, clinical laboratories, medical product manufacturers. *Note:* this course covers liabilities of business entities but does not cover the medical malpractice liabilities of individual physicians.

- Prospective regulatory approaches to promote quality of care and recent initiatives under the federal FDAAA, ARRA, and ACA statutes

- Payers' coverage approval processes and impacts on quality of care (i.e., how does a business with an innovative new product get Medicare and insurers to agree to provide coverage for that new product; such coverage decisions are a make-or-break financial issue for companies that have developed innovative new treatments and products).

- Intro to Texas' framework for oversight of quality of care and patients' rights (UROs, MCOs, TPAs, data access and privacy)

Protecting patients' rights in a transitioning healthcare system

- The shifting balance of state and federal oversight (ERISA and HIPAA preemption of Texas initiatives to protect patient safety and privacy; federal powers to "regulate" the practice of medicine and institutional care delivery after FDAAA).

- State and federal barriers to patients' access to their own health information in clinical settings (impact of the recent CLIA Program and HIPAA Privacy rulemaking; ACMG's 2013 Guidelines on return of results from clinical exome and genome sequencing; state barriers to access to diagnostic information and impacts on the care of chronic disease).

- Protecting patient privacy and data security in the age of "big data" - impact of data sales pursuant to the 2013 Omnibus HIPAA Privacy Rule; EMEA/FDA and PhRMA's clinical trial data sharing initiatives; health information exchanges and large-scale distributed data networks.

- Administering HIPAA's new system of cost-of-service data pricing: impacts on institutions, industry structure and commerce, and patients' rights.

- First Amendment limits on the government's ability to regulate patient safety in an age of informational medicine.

- Anticipated constitutional and statutory challenges to recent federal regulations.