

HEALTH LAW SURVEY

A LAW SCHOOL OUTLINE *by* CORBIN DODGE

Got Outlines?
corbin-dodge.com

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TABLE OF CONTENTS

ABOUT THIS OUTLINE	4
OVERVIEW	5
DISCIPLINE	5
UNLICENSED PROVIDERS	7
MIDWIFERY	7
NURSING, PRACTICE OF MEDICINE	7
New Delegation Statute	7
Retail Clinics	7
effective 2/2014	
NURSING HOMES	8
CHAPTER 3: THE PROFESSIONAL-PATIENT RELATIONSHIP	9
THE CONTRACT B/W PATIENT & PHYSICIAN	9
EXULPATORY CLAUSES	9
INFORMED CONSENT	10
INFORMED CONSENT PROVISIONS	11
HIPAA (A.K.A. THE PRIVACY RULE)	12
EMERGENCY CARE	14
The Good Samaritan Statute	14
Burden of Proof	14
Statute Of Limitations On Health Care Liability Claims	14
Expert Witnesses	15
LIABILITY OF HEALTH CARE INSTITUTIONS	16
HOSPITAL LIABILITY	16
DUTIES TO TREAT PATIENTS	16
CORPORATE NEGLIGENCE	16
Evidence of SOC for Negligence	16
TX Corporate Practice of Medicine Doctrine	17
Cascading Errors Problem, p.195	17
TORT LIABILITY FOR MANAGED CARE	18
REGULATING PATIENT SAFETY QUALITY OF CARE, p.247	18
HEALTH CARE COST AND ACCESS: THE AFFORDABLE CARE ACT	19
Problem: Help From Health Care Reform, p.285	19
Informal Proceedings	21
QUALITY CONTROL; LICENSING	25

DISCIPLINE	25
TX MEDICAL PRACTICE ACT	25
DUTIES TO TREAT	26
ABILITY TO PAY	26
PHYSICIANS DUTY TO TREAT.....	26
CL Approach	26
Today	26
EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA)	27
Problem: EMTALA and HHS Regulation	28
AMERICANS WITH DISABILITIES ACT (ADA)	28
TITLE VI CIVIL RIGHTS ACT OF 1964.....	28
PROBLEM: THE HEALTH FAIR	28
Part I.....	28
Part II.....	28
PRIVATE HEALTH INSURANCE & MANAGED CARE REGULATION	29
MINIMUM ESSENTIAL BENEFIT & COST-SHARING REQUIREMENTS	29
Problem: Insurance Reforms, p. 356.....	29
DISCLOSURE REQUIREMENTS.....	29
EMPLOYEE RETIREMENT AND SECURITY ACT OF 1974 (ERISA)	30
29 U.S.C. § 1144.....	30
ERISA In a Nutshell.....	31
A.	31
B.	31
C. DRUG PROGRAMS.....	31
D. MANAGED CARE.....	31
MEDICARE VS. MEDICAID	31
MEDICAID EXPANSION	32
Problem: Medicaid Eligibility, p. 441.....	32
PROFESSIONAL RELATIONSHIPS IN HEALTH CARE ENTERPRISES	34
STAFF PRIVILEGES AND HOSPITAL-PHYSICIAN CONTRACTS	34
Reviewing the Merits of Privileges Decisions.....	34
Health Care Quality Improvement Act (HCQIA)	34
Problem: p. 491-492 (Dr. Bennett).....	35
LABOR AND EMPLOYMENT.....	35
Employment at Will.....	35
MEDICARE & MEDICAID FRAUD AND ABUSE	36
OVERVIEW: THE 3 STATUTES.....	36
CIVIL FALSE CLAIMS ACT	37
Government Enforcement.....	37
QUI TAM ACTIONS.....	37
The Statute	38
ANTI-KICKBACK STATUTE.....	39
Problems: Advising Under the Fraud and Abuse.....	40
Safe Harbor Provisions	40
problem p. 626 (group practices)	40
Practice problem (handout)	40
STARK LAW	42
The Statute	42
DIFFERENCES B/W AKS VS. THE STARK LAW	43
Problem: Group Practices	43
CONTRACEPTION, ABORTION AND STERILIZATION	44
CONTRACEPTION & ABORTION, P. 713-748.....	44
Problem: State Abortion Laws p. 758 - 760	45
CHAPTER 16: LIFE AND DEATH DECISIONS	46
P. 767-778	46
Problem: Christian Scientist in the ER p. 785	46
ADULTS WITH DECISION-MAKING CAPACITY P. 785-800.....	46
FUTILE TREATMENT, P. 853-863.....	46
TX Futility Statute	46
Problem: With which policy do you agree? (Texas statute, Christus St. Vincent, or Froedhert Hospital)	47
CHAPTER 17: MEDICALLY ASSISTED DYING	48

CONSTITUTIONAL FRAMEWORK, P 865-882	48
FINAL EXAM REVIEW	49
EXAM TIPS	54

ABOUT THIS OUTLINE

A Note About this Outline

My outlines utilize the styles feature in Microsoft Word. An investment of your time in learning how to use the styles feature will allow you to use some of Microsoft Words most powerful features. But be warned, styles can be tricky. The styles that are used in this document are demonstrated below. The Table of Contents can be dynamically updated because it is based on these styles. To learn more about the benefits of using styles, as well as tips and tricks, visit _____. For more outlines, visit www.corbin-dodge.com.

FAQs

How do I apply a different font to any style?

On the main menu, select Format/Style. Highlight the style that you would like to modify. Select modify. Choose your font. Make sure that the option to “Automatically update style” is not checked. Click Apply.

How do I update the Table of Contents?

Right-click and select “Update Field.” Choose the option to update all page numbers.

H1 (OPTIMIZED FOR HELVETICA, 16 PT)

H2

List paragraph (+Bold) (Optimized for Helvetica 9pt)

- List paragraph
- List paragraph (+ indent)
- List paragraph (+ indent)
- etc.

H3

List paragraph (+Bold)

- List paragraph
- List paragraph (+ indent)
- List paragraph (+ indent)
- etc.

Fancy text (Optimized for Hoefler Text, Regular)

OVERVIEW

3 Areas of Course Coverage

- Liability
 - Medical Error
 - Mistakes
 - Unnecessary Services
 - Medical Malpractice
 - Regulation of Hospitals & Nursing Homes
 - Hospital Liability
 - Liability of Managed Care Orgs
- Delivery
 - Cost
 - Cost control strategies (especially ACA)
 - Access (Medicare, Medicaid, Children's Programs, Employer-provided Insurance)
 - Uninsured & ACA
 - Managed Care
 - Professional Relationships (staff privileges, Labor & Employment Law, ADA, Civil Rights §)
 - Fraud & Abuse (FCA)
 - Stark Law
- Ethics
 - Bioethics (right to die, right to effective pain control, physician-assisted death,
 - When does life begin (Reproductive law, cloning, surrogates, etc)
 - Decisional Capacity (newborns, children, adults)
 - Quality, Human Subjects

Standard of Review: Whether it is so arbitrary, capricious or unreasonable so as to constitute an abuse of discretion

DISCIPLINE

Rule: Board has authorization to regulate the practice of medicine.

- There must be some substantial evidence in the record that supports what the board did. *In re Williams, 3*
- The standard of review on appeal is substantial evidence
- On rare occasions the hearing officer or the Administrative Law Judge (ALJ) may overrule the board *Hoover, 5*

- Intractable Pain Treatment

- **Applies:** When cause of pain can't be removed or treated
- **Rule:** Physician not subject to discipline for drugs prescribed in treating patients for intractable pain Tex. Occ. Code § 107.151

- Controlled Substances Act

- Gives DEA authority to regulate the prescribing of controlled substances
- Conflict w/ state medical marijuana laws & federal law. Obama issued order allowing states to stop enforcement
- Conflict w/ state & federal law over prescriptions given for physician-assisted suicide
 - OR Death with Dignity § was upheld b/c physicians have authority to decide what is best in the treatment of pts

- Healthcare Quality & Affordability Act

- Boards must *inquire* into disciplinary actions against board applicants
- Disciplinary orders constituting a change in their practice must be *reported*
 - Health care facilities
- **Who must report actions against physicians:** Medical Board, DEA, Insurance Co's must report malpractice payouts

- Nat'l Center for Natural and Alternative Medicine

- **Allopathic Physicians (M.D.):** Regular doctors
- **Osteopathic Physicians (D.O.):** No discrimination
- **Homeopathic Medicine:** Fighting fire w/ fire, Some states allow practice of homeopathy
 - **Rule:** Board determines whether the state SOC permits homeopathy

In re Guess, 14

Practicing Medicine: diagnosis, treatment, or offer to treat a mental or physical disease or disorder or a physical deformity or injury by any system or method, or the attempt to effect cures of those conditions, by a person who

- a) publicly professes to be a physician or surgeon; or

- b) directly or indirectly charges \$ or other compensation for those services. Tex. Occ. Code § 151.002 (13)
- **Sum:** If their diagnosing or treating patients + call themselves a doc or charge \$ for services → they're practicing medicine

Clinical Trials

- **Phase I Trials** test for toxicity
- **Phase II Trials** test for effectiveness
- **Phase III Trials** (a.k.a. multi-center trial) refines the dosage. Can market drug upon successful completion
- **Phase IV Trials** are post-marketing trials that follows drug recipients & records adverse events

Off-Label Use of Drugs

- Any approved drug may be prescribed by physician
- e.g., glaucoma drug causes growth of thick eyelashes, so may have cosmetic uses

tmb.state.tx.us

UNLICENSED PROVIDERS

MIDWIFERY

Assistance w/ childbirth by one whose practical experience provides comfort to the mother is not nursing under the Nursing Act for which licensure is req'd *State Board of Nursing and State Board of Healing Arts v. Ruebke, 20*

TX

- Has certified nurse midwives, which is an RN 4 year degree
- Also has midwives. Only requires license & a test

NURSING. PRACTICE OF MEDICINE

Nurses can act w/in their licensing and under the standing orders and protocols of a physician *Sermchief v. Gonzales, 28*

2 Models for Nursing

- Nursing Model
 - 2 year and 4 year degree, APNs, Nurse Anesthetists, Pas
 - APNs believe they are competent to work w/out physician and are competent to act independently as practitioners
- Medical Model
 - Work under physician supervision e.g., nurse practitioners
- **TX: Medical Model.** All nurses of any level must work under physician supervision
 - **4 issues of Contention by TX Nursing Board**
 - Degree of Independence
 - Prescriptive Authority
 - Reimbursement of Nurses by Health Plans
 - Etc

NEW DELEGATION STATUTE

EFFECTIVE 2/2014

- Physician may delegate. Delegating physician remains responsible for delegating acts
- Delegation for Prescriptive Authority (main) § 156.0512
 - Written agreement is just b/w doctor & APN
 - Must describe a general plan, referral, emergency process, patient communications, how info is shared
 - Must provide for physician to do a chart review
 - Amount of reviews up to their written agreement
 - Must have monthly e-communications for first 3 years, thereafter that quarterly meetings
 - Can delegate up to 7 *physician extenders* (was 3)

RETAIL CLINICS

- **Pros:**
 - Ease of access
 - More time
 - Lower cost
 - Insurance broadly accepted
 - Preventive services cost may drop b/c free under ACA
- **Cons:**
 - Differential education & training
 - Differential Quality of Care
 - Lacks continuity of care makes it hard to develop physician-patient rlshp
- **TX:** Developed slower b/c req't for physician supervision; lay corps can't employ physician (must be by contract)
- **ACA:** Insurance will cover APNs → lower cost of preventive care; may address physician shortage

NURSING HOMES

Hospitals

Acute Care

Paid by private insurance or Medicaid

Medicare

Utilized for long-term care

Dual-Care: If < 65 & poor

Nursing Homes

Long-term care

Commonly paid by Medicare, often supplemental

Medicaid

Program for the poor

- *In re: The Estate of Michael Patrick Smith v. Heckler*, 43

-

- 1) Standard Settings

- 2) Survey

- 3) Settings

-

- Ability of the state to regulate services

Penalties: Can be administrative penalty or fine; monitoring; ~~pre-'87 could only grant or revoke the license~~

Role of Joint Commission (formerly Joint Commission for Accreditation of Healthcare Professions JCAHO)

- Website sets out standards for hospitals

- Most hospitals are JC-accredited, nursing homes aren't

- Must have Medicare certification, Medicaid certification, & ?

- But if you have JC-accreditation, then the above statuses are deemed present

3 Levels of Protection

- 42 U.S.C. § 1396r

- C.F.R. (Administrative Code)

- C.M.S. (Agency in charge of enforcement)

Discharge

- Long process, 30-day notice provision, notice to the family, must be b/c:

- Facility can't provide the level of care needed

- No longer requires the level of care

-

- Facility Closing

Problem: Residents' Rights, p.49

- Francis Scott

- Nursing home might, w/ notice, and if reasonable, restrict visitation hours. But social activities are encouraged

- Nursing home might, w/ notice, have a no-alcohol policy

- Emma Katz

- *Soft Restraints:* The rules do not allow soft restraints "as needed." Even if there is a physicians order, the rules must still be followed. It is ultimately the responsibility of the facility to enforce the rules. Restraints may not be used for staff convenience. When necessary, they are only allowed for brief periods when the patient needs emergency care

- *Bedrails:* Not an effective use of restraints b/c studies show that residents attempt to crawl over it

- *Pharmacologic Drugs:* Must be part of a care plan, consent, reasonable (see specifics in rules)

CHAPTER 3: THE PROFESSIONAL-PATIENT RELATIONSHIP

The existence of a physician-patient relationship is crucial to the recognition of a legal duty. *Esquivel v. Watters*, p.59.

Once the physician-patient relationship is established, the law imposes a higher duty on physicians—a fiduciary duty¹. The physician undertakes to act in the best interest of the patient, expected to be free of conflicts, etc. Physicians are then subject to an obligation of continuing attention.

TX: When a physician-patient Relationship is Created: There must be some formal step taken

Independent Medical Exams

- It is for a narrow purpose
- Generally consent is specific to the examination. Physician has a duty to conduct the exam in a non-negligent manner. However if something else is discussed, then a higher duty may arise.
- e.g., When a physical is conducted for employment
- e.g., When an exam is paid for by an employer, such as when you're injured on the job
- e.g., When an exam is conducted for an insurance co. checking on insurability

THE CONTRACT B/W PATIENT & PHYSICIAN

- The physician-patient relationship can be considered initially as a contractual one. A duty exists when the physician is under an obligation to use some care to avoid injury to the patient.

Was there a duty? Δ was under an **obligation** to use some care to avoid injury to the patient?

Factors to Consider:

- Whether the physician was in a unique **position to prevent harm**
- Burden of proving harm
- Whether π **relied** upon the physician's diagnosis or interpretation
- **Closeness of the connection** b/w Δ 's conduct & the injury suffered
- **Degree of certainty** that π has or will suffer harm
- **Skill** or special **reputation** of the actors
- Public Policy

On-Call physicians: Usually there is an obligation to be available at the time that the patient arrives.

No Duty to Treat: Absent a physician-patient relationship there is no duty to treat. Physicians thus, may refuse to treat a patient, so long as a physician-patient relationship

EXULPATORY CLAUSES

Tunkl v. Regents of Univ. of Ca.

Of the factors, she mentioned, the superior bargaining strength, essential nature
Exculpatory clauses that would release the hospital from liability are against public policy

Arbitration Agreements

¹ Such as when a "principal" manifests assent to an agent that the agent shall act on the principals behalf and subject to the principals control such that the agent manifests assent

² *White v. Harris*, p.64

- Tex. Health and Safety Code § 74 = TX Medical Liability Statute
Tex. Health and Safety Code § 74.451 Arbitration Agreements
- Not popular b/c patient must consult w/ a lawyer

HMO K's w/ --Insured

- Docs, specialists/ Hospital, Rehab/Labs, etc (K's are created w/ each) & Employer (ee's are called "subscribers")
-

INFORMED CONSENT

Part I. Standard of Duty to Disclose is what a **reasonably prudent patient** would like to know under the circo. *Canterbury v. Spence*, p.78

Part II. Had the undisclosed risk been disclosed the patient would not have undergone that procedure

Generally

- Must disclose medical info even if the procedure is non-invasive
- *Treatment Alternatives*: Should disclose alternatives that are generally acknowledged w/in the medical community as feasible
- Physician is delegated to creating informed consent

Disclosure of Physician-Specific Risk Info, p.92

- Physicians don't have a duty to reveal physician-specific risks so long as they are competent
- e.g., Never provided that treatment
- Must reveal if you ask
- Must post their medical licenses
- Physician an alcoholic → Not req'd to disclose
- If asked about alcoholism → They may be protected, to some extent, by the A.D.A.

Disclosure Requirement for Diagnosis of Terminal Illness

- Physicians are hesitant to law out raw statistics
- Best to ask questions & use that to determine how much you want to know

Physician Payment Sunshine Act (PPSA)

- Under the ACA, a new website will
- Drug companies req'd to disclose any payments made to physicians
 - PPSA requires that manufacturers of drugs, devices, biologics, medical supplies or other items covered by Medicare or Medicaid must submit to Secretary of HHS a list of physicians & teaching hospitals they've made payments to
 - Manufacturers must disclose if they've made a payment or contribution to any other party at the request of a covered entity
 - ACA requires that certain dr's who refer patients for certain radiology tests (incl. MRI's) in which doctors have an ownership interests. Must be in writing.

Decision Aids, p.89

- Per ACA, DHHS must develop a program to create decision aids for preference-sensitive care
- *Preference-sensitive care*
 - Where there's no specific SOC; there are alternatives
 - Idea is that if the patient understands the risks
- They ensure informed consent

TX, see Informed Consent Under TX Law

- It is a "health care liability claim" → Then it falls under Chap 74 of the TCRP, including DAS caps
- Failure to disclose what risks and standards a reasonable person
- A reasonable person wouldn't have submitted to the treatment if they were aware of its risks
- Anything else that occurs at the same time → Pt must understand the risks, etc

Tex. Admin. Code § 601, [see TX Informed Consent List A & B](#)

- **Don't need to know everything on the list !!!**
- If it's on list A & Physician...
 - ...DOES disclose that risk → Rebuttal presumption physician WASN'T negligent in providing informed consent
 - Must be in writing, signed by the patient & a witness
 - ...does NOT disclose that risk → Rebuttal presumption the physician WAS negligent
- If it's on list B
 - No disclosure of informed consent is req'd

- There's a rebuttal presumption the physician WASN'T negligent in providing informed consent

Duties of a Hospital to Provide Informed Consent

- Duty to get the informed consent form in the patients medical record
- **Clinical Trials / Experimental Procedures**
 - Hospital has a duty to disclose & obtain informed consent
 - Procedurally it goes through the hospital's IRB

Humphers v. First Interstate Bank

- Tex. Occ. Code § 109.002 (?)

INFORMED CONSENT PROVISIONS

Theory of Recovery

TX CPRC § 74.101

In a suit against a physician or health care provider involving a health care liability claim based on failure to disclose or adequately disclose the risks and hazards involved in the medical care or surgical procedure rendered by them, the only theory to obtain recovery is **negligence** in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent.

Medical Disclosure Panel

TX CPRC § 74.102

(a) Determines which risks and hazards related to medical care and surgical procedures must be disclosed by to their patients or persons authorized to consent & establishes the form and substance of such disclosure.

(b) It's administratively attached to the TXDH. At disclosure panels request, TXDH shall provide administrative assistance to the panel; and they'll coordinate responsibilities to avoid unnecessary duplication of facilities and services. TXDH at panels request, shall submit the panel's budget request to the legislature. The panel shall be subject, except where inconsistent, to the rules and procedures of the TXDH; however, the duties and responsibilities of the panel shall be exercised solely by the disclosure panel, and the board or TXDH shall have no authority or responsibility with respect to same.

(c) Disclosure panel = 9 members, w/ 3 members licensed to practice law in this state and 6 licensed to practice medicine in this state. Members selected by the commissioner of health.

(d) When term expires → commissioner shall select a successor who serves for 6 years, or until his successor is selected. Any member absent for 3 consecutive meetings w/o consent of a majority of the panel present at each such mtg may be removed by the commissioner at the request of the panel (in writing & signed by chairman). Upon the death, resignation, or removal of any member, the commissioner shall fill the vacancy by selection for the remainder of the term

(e) Can't compensate panel but can reimburse them for necessary expenses, including travel

(f) Panel mtgs shall be held at the call of the chairman or petition of 3+ members. If any panel member is physically at a meeting → other panel members may attend t by conference call (etc) to establish a quorum or vote or any other mtg. subject discussed is irrelevant. The method:

- (1) is subject to the notice req'ts re meetings
- (2) must specify the location
- (3) must be open to the public &
- (4) must provide 2-way communication b/w all members + must stop if audio disrupted

(g) 1st meeting/year → panelists pick 1 panel member as chairman + 1 vice chairman. 1 year term. Chairman presides. Vice Chair in his absence.

(h) TXDH Employees shall serve as the staff for the panel.

Duties of Disclosure Panel

TX CPRC § 74.103

(a) Panel examines all treatments & surgeries to determine if they do/don't require disclosure of risks and hazards

(b) Panel prepares lists of their decision in (a) & if they do require it → establishes degree & form of disclosure
Disclosure forms must be in English & Spanish.

(c) It's published in the TX Register.

(d) At least annually, or as determined, same as (a) but for new treatments & surgeries. Also revises old lists

Duty of Physician or Health Care Provider

TX CPRC § 74.104.

Before a patient or a person authorized to consent for a patient consents to any medical care or surgery that appears on the disclosure panel's req'd disclosure list, the physician or health care provider shall disclose the risks and involved.

Manner of Disclosure

TX CPRC § 74.105

Consent to medical care that appears on the disclosure panel's list requiring disclosure is effective if it's given in writing, signed by the patient or a person authorized to give the consent and by a competent W, and if the written consent specifically states the risks and hazards that are involved in the medical care or surgery in the form and to the degree req'd by the disclosure panel under [74.103](#).

Effect of Disclosure

TX CPRC § 74.106

- (a) In a suit re: negligent failure to disclose (or adequately disclose) risks and hazards in care or surgery rendered:
- (1) both 74.104 disclosure & failure to disclose based on inclusion of any medical care or surgery on the panel's list for which disclosure is not req'd shall be admissible in evidence and shall create a rebuttable presumption that the req'ts of [74.104](#) + [74.105](#) were complied with & include presumption in jury charge &
 - (2) failure to disclose those risks and hazards is admissible evidence. Rebuttable presumption of a negligent failure to conform to the duty of disclosure include in jury charge;
 - but failure to disclose --< May be no negligence if emergency or disclosure not feasible (otherwise would be negligent)
- (b) If care or surgery is rendered w/ respect to which the disclosure panel hasn't determined if there was a disclosure duty → default duty imposed by law.

Informed Consent for Hysterectomies

TX CPRC § 74.107

- (a) Disclosure panel shall develop materials to inform a patient or person authorized of hysterectomies risks and hazards
- (b) ust be in English and Spanish, and understandable to a layperson.
- (c) Must include
- (1) Notice that refusing it won't result in withdrawal or withholding of any benefits provided by federally-funded program or otherwise affect right to future care or treatment
 - (2) Name of person who provides and explains the materials
 - (3) Statement that patient understands it's permanent, nonreversible & can't get pregnant or bear children;
 - (4) Statement that patient has the right to seek a second opinion
 - (5) Statement that patients informed [of the surgical removal of those organs]
 - (6) description of the risks and hazards involved; &
 - (7) written statement signed by the patient or person authorized to consent indicating that the materials have been provided and explained to them and that they understand the nature and consequences of a hysterectomy.
 - (d) Must obtain informed consent before surgery **unless not reasonably possible b/c life-threatening emergency**.
 - If not reasonably possible → medical records must include a written statement signed by the physician certifying the nature of the emergency.
 - (e) Disclosure panel can't prescribe materials w/o first consulting w/ the TX State Board of Medical Examiners.

HIPAA (A.K.A. THE PRIVACY RULE)

See handout

Applies to:

If it has an identifier connected to it → Covered by HIPAA

Permitted Uses & Disclosures of PHI = **Treatment, Payment, & Health Care Operations**

!!!

- e.g., referral to specialist; ICD10 Codes for payment of a claim; discharge instructions

Psychotherapy Notes

- It's an exception. Patient can't obtain their own records

Enforcement (Office of Civil Rights)

- Dr can't be sued for HIPAA violation, but this doesn't pre-empt state statutes

New 2013 Rules

- Breach notifications must *all* be disclosed to the individual unless there is a very low probability that the PHI has been compromised
- If it's <500 persons involved → Must notify the OCR
- A *breach* is any unauthorized disclosure of PHI
- **Payments in cash to avoid sharing PHI w/ Health Plans**, p. 520
 - When an individual pays cash → they can instruct their provider not to notify their health plan
 - Helps to avoid premium from raising
 - Also helps to avoid denial of renewal (although now that shouldn't happen)
 - Request means there's no reason to submit it to the insurance co

HIPAA § does not create an independent COA !!!

- Can sue for a breach of confidence; can't sue lab tech

Marketing Exception

- There's a marketing exception that allows the provider to send out mailings about treatments
- But can't sell it, duh

Nutshell

- **Applies:** Covered entities (Health Plans, Clearinghouses, Providers that transmit PHI in e- form, Business Associates, BA subcontractors)
- A patient's PHI – Medical records or other health information that identifies or could be used to identify an individual, regardless of its form (electronic, paper, oral)
- **Required Disclosures**
 - 1) to the individual (or representative) who is the subject of the PHI (except psychotherapy notes)
 - 2) to HHS for compliance purposes
- **Permitted Uses and Disclosures of PHI (primarily....)**
 - 1) Treatment
 - 2) Payment
 - 3) Health Care Operations
- **Authorized Uses and Disclosures**
 - An individual's authorization is necessary where disclosure is not for treatment, payment or health care operations (or is not otherwise permitted by HIPAA)
 - Authorization must be valid (specific, signed, dated, etc)–authorization needed to obtain psychotherapy notes– authorization needed to use or disclose PHI in exchange for remuneration, for marketing purposes (except face to face communication, or nominal value gift)
- **Minimum Necessary Standard**
 - Must make reasonable efforts to limit disclosure only to those persons and that PHI necessary to accomplish the intended purpose–w/ exceptions above (authorization, law enforcement, etc)
 - Covered Entity must designate privacy official and develop policies
 - Individuals must be informed of their rights under HIPAA Privacy Practices Notice (all covered entities must provide to all patients)
 - HIPAA Preempts State Law (but not common law tort causes of action)
 - See TX Medical Records Privacy Act Enforcement (Office of Civil Rights)
 - Provides for civil and criminal penalties against covered entities (schedule)
 - HIPAA does not provide for an individual cause of action
- Breach Notification
- Any impermissible disclosure is a breach unless “low probability” of PHI compromise–covered entity must provide notification (including business associates)– <500 persons involved, covered entity must notify OCR.

Standard for Surgeons After Surgery: Duty to make a post-operative inquiry

- Also has a duty to leave post-operative instructions
-
- Local standard is evidence of the SOC but it's not conclusive
- So customs & local standards are relevant, but not conclusive
- TX adopted a nat'l standard (TX rejected the *respectable minority* position)

Practice Guidelines as Alternate SOC

- More focused since ACA

Problem: The Battle of Standards II, p. 145

- ...
- ...
- What is the national SOC
- They fall w/in that particular category

Lost Chance

- Most jsd's would allow recovery of up to 8/20% for a lost chance
- Case says recovery must be a preponderance of the evidence must be 51% or more
- EX: Chance of Survival = **Can't recover 50%** | **Can recover 70% 100%**

EMERGENCY CARE

- Notice of a claim & release of authorization to obtain medical records

THE GOOD SAMARITAN STATUTE

Liability For Emergency Care (a.k.a., Good Samaritan §)

§ 74.151

A person who in good faith administers emergency care is not liable in civil DAS for an act performed during the emergency unless the act is wilfully or wantonly negligent, including a person who:

- Uses an automated external defibrillator or
- Was a volunteer first responder

see § 421.095, Government Code

Doesn't apply to care administered:

- for or in expectation of remuneration, provided that being legally entitled to receive remuneration shall not determine whether the care was administered for or in anticipation of remuneration or
- by a person at the scene of the emergency b/c he or a person he represents as an agent was soliciting business or seeking to perform a service for remuneration

and also doesn't apply to a person whose negligent act or omission was a producing cause of the need for emergency care

BURDEN OF PROOF

Standard of Proof in Cases Involving Emergency Medical Care

§ 74.153

Application of res ipsa loquitur

§ 74.201

- Res ipsa loquitur shall only apply to health care liability claims against health care providers or physicians in those cases to which it has been applied by the AppCt
- "the thing speaks for itself"
- Easier to meet BOP
- e.g., Foreign object left inside; Operation on the wrong body part

STATUTE OF LIMITATIONS ON HEALTH CARE LIABILITY CLAIMS

Generally

§ 74.251(a)

- Must file w/in 2 years from the occurrence of the breach or tort or from the date treatment or hospitalization is completed
- but minors >12 years have until their 14th birthday to file
- Except as provided, this § applies to all persons regardless of minority or other legal disability.

Statute of Repose

§ 74.251(b)

- Must bring it not later than 10 years after the date of the act or omission that gives rise to the claim.
- 2 years from the date of injury and discovery rule must allow a reasonable time
- **Open Cts Doctrine**
 - § is constitutional unless it violates the Open Cts Doctrines → When it's an unreasonable time for π to file suit
 - e.g., 2 months before § runs
 - **Examples**
 - 6 months before § runs → Reasonable time to file suit
 - 1 month before § runs → Unreasonable time
 - If injury is not discovered 1 month before statute of repose → Ct says § is constitutional and you may file

(2013 Revision) § 74.351

(a) In a health care liability claim, a claimant shall, not later than 120 days after the date each Δ's original answer is filed, serve on that party or their attorney 1+ expert reports, w/ a CV of each expert listed for each Δ against whom a claim is asserted.

May extend the date for serving it by written agreement of the parties.

Each Δ whose conduct is implicated in a report must file & serve any objection to the sufficiency of the report no later than [the later of the]

- 21 days after it's served or
- 21 days after Δ's answer is filed, whichever is later
- [Applies only to an action commenced on or after 9/1/2013. Otherwise it's governed by the law in effect before then]
- Δ's response must be 21 days after the experts report is served or
- Expert report must be made w/in 120 days of Δ filing their answer

whichever is later

EXPERT WITNESSES

Expert Ws Qualifications in a Suit Against a Physician

In a suit involving a health care liability claim against a physician for injury or death of a patient, a person may qualify as an expert W re: whether the physician departed from accepted SOC only if:

§ 74.401(a)

- Physician
- Practices medicine when testimony given or when the time claim arose &
- Knowledge of accepted SOC for the diagnosis, care, or treatment of the illness, injury, or condition &
- *Training or experience* qualifies them to offer an expert opinion about those standards
 - Are they board-certified? **OR**
 - Other substantial training or experience in another area of medical practice that's relevant & practices medicine in rendering care relevant to the claim.

[Practicing Medicine or Medical Practice] includes:

§ 74.401(b)

- Residents or students at an accredited medical school
- Osteopathy
- Consulting physician to other physicians who provide direct patient care, upon request

If Ct departs from (a)-(c) → Ct must state a good reason why in the record

§ 74.401(d)

Pretrial objections to W qualifications

§ 74.401(e)

Must make **w/in 21 days after they receive W's CV or the date of W's deposition**

- Unless...
 - Couldn't reasonably anticipate & good faith basis for the objection &
 - No previous objections
 - ...then must object as soon as practicable
- When
 - Ct shall conduct a hearing as soon as practicable after objection received, before trial (if possible)
 - If not enough time to conduct hearing before trial → Hearing done outside the jury's presence
 - Can still question W about their qualifications at trial

A Δ physician can still qualify as an expert

§ 74.401(f)

Physician

§ 74.401(g)

- Licensed to practice in 1+ states **or**
- Graduated from a medical school accredited by the Liaison Committee on Medical Education or the American Osteopathic Association only if testifying as a Δ and testimony relates to that Δ's SOC, the alleged departure from SOC, or the causal relationship between the alleged departure from that SOC and the injury, harm, or DAS claimed.
- Expert should be practicing medicine. Not a req't that expert is certified in the same specialty
See Expert Reports Class Exercise

LIABILITY OF HEALTH CARE INSTITUTIONS

HOSPITAL LIABILITY

Intro

- Big push toward integrated hospital systems e.g., Houston Methodist network of hospitals
- Larger systems are better equipped to ensure delivery standards
 - e.g., must comply w/ e-medical records & reporting req'ts to be part of the system

Vicarious Liability & Employees in the Hospital Setting

- Hospitals are vicariously liable for the negligent action of it's employees. A hospital may be reached w/ vicarious liability only when a **doctor is an employee** of it and **whose negligence injured a patient !!!**
 - Includes everyone: dieticians, medical records specialists, admins, etc.
- **Test: Whether a physician is an employee** p.174
 - Look to the extent of control which, by agreement, the [hospital] may exercise over the [physician's] work
 - Based upon agency theory
- (1) Π must show they have a reasonable belief the physician was an agent or employee of the hospital
- (2) The physician was an employee?
- (3)
- *Burless v. West Virginia University Hospitals, Inc.*, p.171

TX: Hospital-based physicians are generally considered independent contractors

Other jurisdictions recognize hospital-based physician's as employees b/c their roles are considered an inherent function of the hospital

Includes: anesthesiologists, radiologists, pathologists, ? (and hospitalists & intensivists)

Emerging SOC's: When a new SOC is established, hospital should immediately act..

DUTIES TO TREAT PATIENTS

Hospital's Duty to Obey Instructions of a Doctor

Muse v. Charter Hospital of Winston-Salem, Inc., p.184

- A hospital may not have a discharge policy that is contrary to the physician's order
- e.g., Can't say when insurance expires, patient must be discharged if contrary to physician's orders
- **New:** No annual limits, lifetime limits, or drop of insurance coverage allowed

CORPORATE NEGLIGENCE

Compare

NEGLIGENCE FOR THE HOSPITAL

Where a 3P was negligent

CORPORATE NEGLIGENCE

Where hospital can be held liable *even when no 3Ps are brought into the case*

Elements of Corporate Negligence

- 4 Categories of a Hospital's Duties

Thompson v. Nason Hosp., p.187

- Duty to maintain facilities and equipment
 - e.g., holds itself out to the community as a place to delivery babies → Must have facilities, etc
- Duty to select & retain only competent physicians
- Duty to oversee all persons who...
- Duty to maintain adequate policies

EVIDENCE OF SOC FOR NEGLIGENCE

Joint Commission Standards

- *Considerations:* Practice patterns

e.g., unnecessary dx tests

Medicare Certification Standards

- Certified by Joint Commission → they're deemed to meet the Medicare Cert. Standards
- 2008 Medicare Improvement for Providers and Patients Act

HIQUAI: Requires hospitals to check the National Practitioner Data Bank (NPDB) when granting or renewing staff privileges

TX CORPORATE PRACTICE OF MEDICINE DOCTRINE

- Mandates that doctors can't be employed by lay corps
- **Exceptions**
 - Teaching hospitals can employ physicians e.g., UT School of Health
 - School Districts
 - Counties > 50,000 (b/c difficult to attract physicians out to rural areas w/o a guaranteed salary)
- **Justification:** Doctors can't have allegiance or loyalties to their patients as well as their corps
- ACA encourages

CASCADING ERRORS PROBLEM, P.195

- Look to corporate negligence, b/c just staffing a pediatric resident in the E.R. is not adequate staffing
- *"Breached it's own protocols by hiring him...who had not been properly screened"*
 - A hospital has a corporate duty to have some policies & practices in place that they follow.
 - Even if they have good protocols in place → they must follow them for them to be effective
- *re: the transfer*
 - Hospitals must have a transfer policy in place.
 - Here, the patient has asked to be transferred.
 - The Federal Emergency Care Statute has a provision about that. Nurses should know what the transfer policy is, if they have one.
- *Re: nurses failure to notice*
 - If nurses are negligent → you always have vicarious liability under the theory of respondeat superior.
 - They can also be individually negligent.
- *IV fluids were not administered properly*
 - Same, negligent liability for the nurse, vicarious liability for the hospital
- *Re: Drugs contraindicated for patient*
 - Doctor is negligently delegating to the nurse → Doctor can be liable. Has roots in the Borrowed Servant Doctrine
- *Re: Laryngoscope couldn't be used & Epinephrine not available*
 - Corporate negligence, Hospital has a specific duty to have adequate equipment
- *Re: Defense*
 - He has some protection under state statute, for emergency physician exercising care in good faith

See Organizing the Health Care Enterprise Handout

- **Types of Privileges**
 - Admitting
 - Clinical
 - Letter defines what they are: what procedures they can use, etc.
 - May limit to consulting privileges
- Medical Staff has a credentialing committee, etc.
- Any time a physician's privileges are limited → It's supposed to be reported to the Nat'l Practitioners Data Bank (NPDB)
 - But hospitals don't always comply

Larson v. Wasemiller, p.196

- Must conduct their investigation based in good faith based on info they have
- HIQUIA provides immunity from...
 - ...If the suit is against the hospital on a theory of corp liability → Committee proceedings may prove vital to establishing a hospital's liability, committee proceedings are usually immunized from admission into evidence by statute if pt can obtain the info another way
 - But they can lose their immunity if they don't query the NPDB !!!
- **TX:** Uses language out of Federal Statute: As long as they act in good faith and w/o malice
 - But most states who have applied that language usually apply it to doctors

- TX applies it to peer review committees !!!
- So how does a pt show that? Hard, unclear

Hospitals do not have a duty to disclose, but they do have a duty to avoid misleading statements

Kadlex Medical Center v. Lakeview Medical Assoc., p. 202

TORT LIABILITY FOR MANAGED CARE

Fee for Service

- | | | |
|---|------------------------|---------------------------|
| - Straight fee for Service is when the patient pays the physician | Dr, etc controls costs | → Incentive for more care |
| - Insurance pays physician and patient may pay part | Dr, etc controls costs | → Incentive for more care |

HMO

- **Hallmarks of an HMO**
 - Limited Network of Providers
 - Must designate primary care physician who is a *gatekeeper* to the specialist
 - Utilization review process
 - Someone decides what's covered
 - Capitation
 - How physicians are paid in traditional HMO model
 - Physicians are paid per member, per month \$6-\$8 generally
 - Paid a set pol of \$, w/ costs deducted (which is a disincentive to providing care)
- Controls not only the delivery of the care, but also the costs
- HMO K's w/ doctors, hospital,
- *Utilization Review*: A determination of what is medically necessary
 - E.g., is physician over-ordering
- So HMO can hire drs w/ a lower cost, less orders, etc.
- **TX**: expressly allows HMO by statute

Preferred Provider Organization (PPO)

- **Apparent Authority**
 - Did the [provider of care/HMO/etc.] hold itself out as the provider of care?
 - Did the [provider of care/HMO/etc.] provide that care?
 - Π must justifiably rely
 - Did they choose that physician?
- **Implied Authority**
 - Did the physician have actual control? E.g., how specific control is over office hours, etc
- An HMO may be held vicariously liable for the negligence of its independent contractor physicians
 - *Petrovich v. Share Health Plan of Ill.*, p. 216
- Corporate negligence also applies to managed care organizations (HMOs) *Shannon v. McNulty*, p.229
 - e.g., duty to have adequate policies in place

REGULATING PATIENT SAFETY | QUALITY OF CARE, P.247

She breezed over it

HEALTH CARE COST AND ACCESS: THE AFFORDABLE CARE ACT

Groups who have difficulty w/ access/insurance Coverage

- p.18-25
- p.50-64
- Laid off
- unable to obtain work but not yet eligible for Medicare

- Single-payor systems

- Treaties w/ native Americans
- Prisoners
- Medicaid Program for the Poor
- Medicare Program for the Elderly
- CHIP Program for children
- Public Safety Net Program

e.g., public hospitals, public clinics

- About ½ US citizens receive private insurance through employers

How ACA Provides Access to Health Care

- Premium Assistance: Help w/ tax credits
- Help w/ cost-sharing

e.g., plan pays 80%, you pay 20%

- 3 ways \$ comes out of your pocket

- *Deductibles*: \$ you pay out-of-pocket before insurance kicks in
- *Co-Insurance*
- *Co-payment*

e.g., \$20 co-pay

ACA Premium-Assistance Tax Credits

- Not really a credit to you → gov't gives it to the private insurance you indicated
- If you make over 400% of the federal poverty level, and you got tax credits → you have to pay \$ back !!!
 - (probably not all, there's caps but they keep changing the cap, 3x)

PROBLEM: HELP FROM HEALTH CARE REFORM, P.285

How large a premium assistance are they eligible for? $12K - [200\% \times 6.3] = 12K - [6.3\%] \times 32K$

Is he eligible for premium-assistance tax credits?

- EE may buy on exchange if their share of plan costs exceeds 9.5%
- He must pay \$2,500 out-of-pocket but his salary is 18,000, so his share exceeds 9.5%

Is he eligible for cost-sharing reduction payments?

Is she eligible for premium-assistance tax credits? No

Is she eligible for cost-sharing reduction?? No

Is she eligible for premium-assistance tax credits?

- Cost of plan - [lowest = 12K]
- Cost of plan – 12,000 = 4875 (this is her premium tax credit)
- She's at 300% of the fed poverty level
- $.095 \times [\text{income} = 75K] =$

How much was their tax credit?

It was \$832
 $2667 \times 12 = 22,004$ so we know they're at 200% of household income

How much will they need to pay back?

\$2,696

ACA 4 Rules for Problem

- **1. Allows people to go to healthcare.gov and see plan choices:** Platinum, Gold, Silver, & Bronze (& other hardship plans)
- **2. Cost-Sharing:** Persons b/w 100%-150 of Federal Poverty Level
- **3. Tax Credit:** Americans earning up to 400% of poverty level are eligible for tax credit
 - Rule/Formula: [The cost of silver plan — \[the product of the “applicable % and household income\]](#)
- **4. Employment:** EE may buy on exchange if their share of plan costs exceeds 9.5%

- Massachusetts has Romneycare, which is an individual mandate
- TX Bar has its own private exchange insurance

Disciplinary Authority Of Board; Methods Of Discipline.

§ 164.001

(a) Except for good cause shown, the board, on determining a violation of this subtitle or a board rule or for any cause for which the board may refuse to admit a person to its examination or to issue or renew a license, including an initial conviction or the initial finding of the trier of fact of guilt of a felony or misdemeanor involving moral turpitude, shall:

- Reprimand **or**
- Revoke or suspend license **or**
- Place on probation a person whose license is suspended

(b) Except as otherwise provided by §§ 164.057 & 164.058, the board, on determining that a person committed an act from 164.051-164.054, shall enter an order to:

- (1) deny their application for a license or authorization to practice
- (2) administer a public reprimand
- (3) suspend, limit, or restrict their license or authorization to practice, including:
 - Can limit or exclude their scope of practice
 - Can require periodic board review
- (4) revoke their license or authorization to practice
- (5) require them to get care, counseling, or treatment to renew their license or to continue practicing
- (6) require they to participate in an educational or counseling program prescribed by the board
- (7) require they practice under the direction of another physician for a specified period
- (8) require public service **or**
- (9) assess an administrative penalty (§165.001)

e.g., can't do X

(c) If board determines they pose a continuing threat to the public welfare → Board must revoke, suspend, or deny a the license

(d) Board may also issue a written reprimand or require that they participate in CME programs. ...shall specify the programs to be attended & the # of hours that must be completed

(e) For any sanction imposed under this chapter as the result of a hearing conducted by the State Office of Administrative Hearings, that office shall use the schedule of sanctions adopted by board rule.

(f) Board must adopt a schedule of the disciplinary sanctions. It must ensure that the severity of the sanction imposed is appropriate to the type of violation or conduct

(g) In determining the disciplinary action, including the amount of any administrative penalty to assess, the board shall consider:

- (1) if being disciplined for multiple violations or a rule or order or
 - → Must consider a more severe disciplinary action than would for just 1 violation, including revoking their license
- (2) previously disciplined
 - Must consider revoking their license
 - If they don't revoke it → Must consider a more severe disciplinary action than previously taken
- (and) whether the violation relates directly to patient care or if only an administrative violation.

Remedial plan

§ 164.0015

(a) In addition to 164.001 & 164.002, the board may establish a remedial plan to resolve a complaint investigation re this subtitle.

(b) Can't contain a provision that:

- (1) revokes, suspends, limits, or restricts a person's license or other authorization to practice; or
- (2) assesses an administrative penalty against a person.

(c) Can't be imposed to resolve a complaint:

- (1) concerning:
 - A patient death **or**
 - A felony **or**
 - Inappropriate sexual behavior or contact w/ a patient or Inappropriate personal or financial involvement w/ a patient; or
- (2) in which the appropriate resolution may involve a restriction on the manner in which they practice medicine.

(d) Board can't issue a remedial plan to resolve a complaint against a license holder if the license holder has previously entered into a remedial plan with the board for the resolution of a different complaint relating to this subtitle.

(e) Board may assess a fee to recover the costs of this plan.

(f) Board shall adopt rules necessary to implement this

Board disposition of complaints, contested cases, and other matters

§ 164.002

(a) Unless precluded by law, the board may dispose of any complaint or matter relating to this subtitle or of any contested case by a stipulation, agreed settlement, or consent order.

(b) Must by writing & (signed by dr if appropriate)

(c) An agreed disposition is a disciplinary order for purposes of reporting under this subtitle and of administrative hearings and proceedings by state and federal regulatory agencies regarding the practice of medicine. An agreed disposition or a remedial plan under 164.0015 is public info.

(d) In civil litigation, an agreed disposition or a remedial plan under 164.0015 is a settlement agreement under Rule 408, TX Rules of Evidence. This subsection doesn't apply to a license holder who previously entered into an agreed disposition with the board of a different disciplinary matter or whose license the board is seeking to revoke.

(e) The board may not dismiss a complaint solely on the grounds that the case has not been scheduled for an informal meeting w/in the 164.003(b) time req'ts

Delegation of certain complaint dispositions

Board may delegate authority to dismiss or enter an agreed settlement to a committee of board EEs if:

§ 164.0025(a)

- if complaint doesn't relate directly to patient care **or**
- involves only administrative violations.

Must approve at a public mtg

Must refer for informal proceedings if:

§ 164.0025(b)

- Committee of EEs determines the complaint shouldn't be dismissed or settled **or**
- Committee unable to reach an agreed settlement **or**
- Physician requests an informal proceeding.

INFORMAL PROCEEDINGS

Board shall adopt procedures governing:

§ 164.003(a)

- Informal disposition of a contested case under 2001.056, Govt Code &
- Informal proceedings held in compliance w/ 2001.054, Govt Code

Minimum Requirements

§ 164.003(b)

- An informal meeting (in compliance w/ 2001.054, Govt Code) be scheduled no later than **180 days** after the date the official investigation of the complaint commenced (154.057(b))
- ...**unless board shows good cause for scheduling later &**
 - Gives notice to the physician of the mtg time and place **no later than 45 days** prior to the mtg &
 - Complainant and the physician have an opportunity to be heard &
 - 1+ board members or district review committee members participating as a panelist represent the public &
 - Board's legal counsel or representative of atty general present to advise the board or the board's staff investigation &
 - Board staff member presents to the representative the facts they reasonably believe it could prove by competent evidence or qualified Ws at a hearing.

Physician entitled to:

§ 164.003(c)

- Reply to the staff's presentation &
- Present the facts the reasonably believes he could prove by competent evidence or qualified Ws at a hearing.

(d) After ample time is given for the presentations, the board representative shall recommend that the investigation be closed **or** shall attempt to mediate the disputed matters and make a recommendation re: the case in the absence of a hearing under applicable law concerning contested cases.

(e) If license holder previously disciplined → Board shall schedule the informal meeting as soon as practicable, but not later than the (b)(1) deadline

(f) (b)(2) notice must be accompanied by a written statement of the nature of the allegations and the info the board intends to use at the mtg. If it doesn't → license holder may use it as grounds to reschedule. If the complaint includes an allegation that the license holder has violated the SOC → Notice must include a copy of the report by the expert physician-reviewer. The license holder must provide to the board the license holder's rebuttal at least 15 business days before the mtg in order for the info to be considered

(g) The board by rule shall define circs constituting good cause for purposes of (b)(1), including the extended illness of a board investigator and an expert physician reviewer's delinquency in reviewing and submitting a report to the board.

(h) 164.007(c) applies to the board's investigation file used in an informal meeting under this §.

(i) Must record the informal settlement conference proceeding if physician requests.
Can't release to a 3P (unless authorized under this subtitle).
Board may charge them for this

Board Representation In Informal Proceedings

§ 164.0031

(a) In an informal meeting (164.003) or an informal hearing (164.103) at least 2 panelists shall be appointed to determine whether an informal disposition is appropriate. 1+ panelists must be a physician.

(b) Notwithstanding (a) and 164.003(b)(4), an informal proceeding may be conducted by 1 panelist if the affected physician waives the req't that at least 2 panelists conduct the informal proceeding. If the physician waives that req't, the panelist may be either a physician or a member who represents the public.

(c) The panel req'ts described by (a) do not apply to an informal proceeding conducted by the board (164.003) to show compliance with an order of the board.

Roles And Responsibilities Of Participants In Informal Proceedings

§ 164.0032

(a) A board member or district review committee member that serves as a panelist at an informal meeting (164.003) shall make recommendations for the disposition of a complaint or allegation. The member may request the assistance of a board EE at any time.

(b) Board EEs shall present a summary of the allegations and facts that the EEs reasonably believe may be proven by competent evidence at a formal hearing.

(c) A board attorney shall act as counsel to the panel and, notwithstanding (e), shall be present during the informal meeting and the panel's deliberations to advise the panel on legal issues that arise. They may ask questions to clarify any statement. They shall provide to the panel a historical perspective on comparable cases that have appeared before the board, keep the proceedings focused, and ensure the board's EEs and the physician have an opportunity to present. During deliberations, they may be present only to advise the panel on legal issues and to provide info on comparable past cases

(d) The panel and board employees shall provide an opportunity for the physician and his representative to reply to the board employees' presentation and to present oral and written statements and facts they reasonably believe could be proven by competent evidence at a formal hearing.

(e) An employee of the board who participated in the presentation of the allegation or information gathered in the investigation of the complaint, the physician & his representative, the complainant, the Ws, and the public may not be present during deliberations. Only the members of the panel and the board attorney serving as counsel to the panel may be present during the deliberations.

(f) The panel shall recommend dismissal of the complaint or allegations or, if it determines the physician violated a statute or board rule, the panel may recommend board action and terms for an informal settlement

- (g) Recommendations must be a written order and presented to the physician & his representative.
 - Physician may accept the proposed settlement w/in the time established by the panel at the informal meeting.
 - If physician rejects the proposed settlement or doesn't act w/in the req'd time → Board may proceed w/ filing a formal complaint w/ the State Office of Administrative Hearings.

(h) If the board rejects the panel's recommendation for settlement or dismissal → Board shall notify the physician and state in the minutes the reason and specify further action to be considered. In determining the appropriate further action to be taken, shall consider previous attempts to resolve the matter.

Dismissal of baseless complaint

§ 164.0035

If, during the 180-day period from 164.003(b)(1), the board determines the complaint is baseless or unfounded → Shall dismiss the complaint and include a statement in the records that the reason for the dismissal is b/c it was baseless or unfounded. The board shall adopt rules that establish criteria for determining that a complaint is baseless or unfounded.

Notice regarding certain complaints

§ 164.0036

(a) If informal meeting is not scheduled for a complaint before the 180th day after the date the board's official investigation of the complaint is commenced under 154.057(b) → board shall provide notice to all parties to the complaint.

- Notice must include an explanation of the reason why the informal meeting has not been scheduled.
- Not req'd if it would jeopardize an investigation.

(b) Board must include in its annual report to the legislature...

- Info about any complaint for which notice is req'd under (a), including the reason for failing to schedule the informal meeting before the 180-day deadline.
- Must also list any complaint in which the investigation has extended beyond the 1st anniversary of date the complaint was filed

Compliance With DP Requirements

§ 164.004

(a) Except in a suspension (164.059) or under the terms of an agreement b/w the board and a license holder, a revocation, suspension, involuntary modification, or other disciplinary action relating to a license is not effective unless, before board proceedings are instituted:

- (1) the board gives notice consistent w/ the notice req'ts under 154.053, to the affected license holder of the facts or conduct alleged to warrant the intended action &
- (2) the license holder is given an opportunity to show compliance w/ all req'ts of law for the retention of the license, at the license holder's option, in writing or by personally appearing at an informal meeting with 1+ representatives of the board.

(b) If the license holder chooses to personally appear and an informal meeting is held, the board's staff and its representatives are subject to *the ex parte* provisions of Chapter 2001, Gov't Code, w/ regard to contacts with board members and administrative law judges concerning the case.

Initiation Of Charges; Formal Complaint

§ 164.005

(a) In this section, "**formal complaint**" a written statement made by a credible person under oath that is filed and presented by a board representative charging a person with having committed an act that, if proven, could affect the legal rights or privileges of a license holder or other person under the board's jurisdiction.

(b) Unless otherwise specified, a proceeding under this subtitle or other applicable law and a charge against a license holder may be instituted by an authorized representative of the board.

(c) A charge must be in the form of a written affidavit that:

- (1) is filed w/ the board's records custodian or assistant records custodian &
- (2) details the nature of the charge as required by this subtitle or other applicable law.

(d) The board president or a designee shall ensure a copy of the charges is served on the respondent or the respondent's counsel of record.

(e) The president or designee shall notify the State Office of Administrative Hearings of a formal complaint.

(f) A formal complaint must allege with reasonable certainty each specific act relied on by the board to constitute a violation of a specific statute or rule. The formal complaint must be specific enough to:

- (1) enable a person of common understanding to know what is meant by the formal complaint; and
- (2) give the person who is the subject of the formal complaint notice of each particular act alleged to be a violation of a specific statute or rule.

(g) The board shall adopt rules to promote discovery by each party to a contested case.

Service of Notice

§ 164.006

(a) Service of process to notify respondent of a hearing re the charges must be served in accordance w/ Chapter 2001, Gov't Code.

(b) If service described by (a) is impossible or cannot be effected → Board shall publish 1x/week for 2 successive weeks a notice of the hearing in a newspaper published in the county of the last known practice, if known.

(c) If the license holder is not currently practicing in this state as evidenced by info in the board files, or if the last county of practice is unknown → Published in a Travis County newspaper.

(d) If publication → Hearing date can't be earlier than **10 days** after the date last published

Administrative hearings; confidentiality issues

§ 164.007

(a) Board shall adopt procedures governing formal disposition of a contested case under Chapter 2001, Gov't Code. A formal hearing shall be conducted by an administrative law judge employed by the State Office of Administrative Hearings. After receiving the judge's findings of fact and conclusions of law, the board shall issue a final order based on the findings

(a-1) Notwithstanding 2001.058(e), Gov't Code, the board may not change a finding or vacate or modify an order of the judge. The board may obtain judicial review (see 2001.058(f)(5), Gov't Code). For each case, the board has the sole authority and discretion to determine the appropriate action or sanction, and the judge may not make any recommendation regarding the appropriate action or sanction.

(b) Notwithstanding this subtitle or other law, the board may employ, retain, and compensate:

- (1) attorneys, consultants, and other professionals as necessary and appropriate to serve as board consultants or special counsel to prosecute complaints filed with the board on behalf of the hearings division and investigating division &

- (2) court reporters and other staff necessary to prepare for or represent the board in the hearings
- (c) Each complaint, adverse report, investigation file, other investigation report, and other investigative information in the possession of or received or gathered by the board or its EEs or agents relating to a license holder, an application for license, or a criminal investigation or proceeding is privileged and confidential and is not subject to discovery, subpoena, or other means of legal compulsion for release to anyone other than the board or its EEs or agents involved in discipline. Investigative info includes info relating to the identity of, and a report made by, a physician performing or supervising compliance monitoring for the board.
- (d) Not later than 30 days after the date of receipt of a written request from a physician or their atty, and subject to any other privilege or restriction set forth by rule, statute, or legal precedent, and unless good cause is shown for delay, the board shall provide the license holder with access to all info in its possession that the board intends to offer into evidence in presenting its case in chief at the contested hearing on the complaint. Board not req'd to provide:
 - Investigative report or memorandum
 - Identity of a nontestifying complainant
 - Attorney-client communications, attorney work product, or other materials under privilege
- (e) Furnishing info under (d) doesn't constitute a waiver of privilege or confidentiality
- (f) Investigative info may be disclosed to:
 - (1) the appropriate licensing authority of:
 - another state **or**
 - a territory or country in they're licensed or applied for a license **or**
 - (2) a peer review committee reviewing an application for privileges or qualifications re retaining privileges.
- (g) If investigative info in the possession of the board, its EEs or agents indicates a crime → Report to law enforcement
- (h) The board shall cooperate and assist criminal investigation by providing info that's relevant. It is confidential and can't be disclosed by the investigating agency except as necessary to further the investigation.

Hearings on certain complaints

§ 164.0071

- 164.007 formal hearing where the sole basis for disciplinary action is by 164.051(a)(7) → Board shall provide evidence from the board's investigation that shows the basis for the board's findings req'd by that subdivision.
- 164.007 formal hearing →
 - Info obtained by peer review can't be used as evidence except as opinion of the board's expert W.
 - Peer review committee member not subject to subpoena
 - Can't be compelled to provide evidence in a formal hearing.
 - If admitted into evidence → Must be under seal to protect confidentiality (and for all trials and appeals)

Right to counsel In a disciplinary hearing under this subtitle → respondent entitled to counsel

§ 164.008

Judicial review § 164.009. A person whose license to practice has been revoked or who is subject to other disciplinary action by the board may appeal to a Travis County DC not later than 30 days after the date the board decision is final.

Monitoring of license holder

§ 164.010

- (a) Board must develop a system to monitor compliance w/ the req'ts of this subtitle of physicians who are the subject of disciplinary action.
- (b) Must include procedures to:
 - Monitor for compliance a license holder ordered by the board to perform certain acts &
 - Identify and monitor license holders who are the subject of disciplinary action and who present a continuing threat to the public welfare through the practice of medicine.
- (c) Must immediately investigate:
 - A violation of a disciplinary order by a license holder described by (a) **or**
 - A complaint filed against a license holder described by (a).

License status pending appeal

§ 164.011

- (a) Must give notice to the board, then application to the Ct to enjoin or stay a board's decision on a disciplinary matter
- (b) Can't practice medicine or deliver health care services in violation of a disciplinary order or action while appeal is pending **unless the order or action is stayed**
- (c) Can't grant a stay or injunction if the license holder's continued practice presents a danger to the public **or** for a term <120 days.

QUALITY CONTROL; LICENSING

DISCIPLINE

-

TX MEDICAL PRACTICE ACT

First, we will do the HIPAA problems left from the last class (the class before our guest speaker). Then, we will go on to the assignment reflected on the amended syllabus. If we have time, I would like to go over the key provisions of the Medical Liability Act (Tex. Civ. & Prac. Code Sec. 74). A [LINK](#) to this act is posted on Stanley. You may want to bring a copy of it to class to take notes on the key provisions; or, if you wish, you may just access it on your laptop. There is, however, one important 2013 revision that is not reflected on the state's official website (the Stanley Link). Section 74.351 (a) has been revised, and I have posted that revision to a Stanley file.

DUTIES TO TREAT

ABILITY TO PAY

Overview: Not everyone has equal access to insurance

Disparities in Healthcare

- Race-based disparities
 - In a study African-Americans were less likely to be referred for cardiac catheterization
 - Later studies confirmed

PHYSICIANS DUTY TO TREAT

CL APPROACH

Overview

- Physician-patient relationship is based upon the law of contracts
- Physician could withdraw under CL for lack of payment, but must still give sufficient notice
- A physician or surgeon, upon undergoing an operation or other care, is under [a duty to treat], in the absence of an agreement limiting the service, of continuing his attention after the 1st operation/treatment, so long as the case requires attention. *Ricks v. Budge*, p.308
- A physician has the right to withdraw from a case, but If the case is such as to still require further...attention, he must, before withdrawing, give the patient sufficient notice so the patient can procure other medical attention
 - Physician can withdraw w/ sufficient notice to the patient

Duty to Treat when No Physician-Patient Relationship

- No relationship → No duty
- A physician is not held liable for arbitrarily refusing to respond to a call or a person...urgently in need of medical or surgical assistance provided that the [physician-patient] relationship...does not exist at the time the call is made or at the time the person presents himself for treatment. *Childs v. Weis*, p. 311

TODAY

- Physician has a contractual duty to treat a patient in a medical emergency
- For HMO's → Physician may have a contractual duty to accept any new patient-subscriber, so long as the physician's practice is not full
- Hospital has a duty to treat if it holds itself out as an emergency treatment location

EMTALA Analysis !!!

1. *Does EMTALA apply?*

EMTALA applies only to hospitals that
1) **accept payment from Medicare**, and
2) that **have an emergency department**.

2. *What is the duty of a hospital under EMTALA?*

There are 3 duties of a hospital under EMTALA.

First, a hospital has a **duty to screen**. A hospital must screen a patient if an *emergency medical condition* exists. A hospital must provide the same screening to all patients who present w/ the same symptoms.

Second, a hospital has a **duty to stabilize**.

Third, a hospital has a **duty to....**

Enacted b/c: Hospitals were dumping patients that didn't have insurance—transferred them to public hospital

3 Duties of a Hospital under EMTALA

- **1. Duty to Screen**

- A hospital must screen a patient if an *emergency medical condition* exists
 - An *emergency medical condition* exists for a pregnant woman if she is going into contractions
- To determine medical condition
 - Acute condition requiring emergency medical care
 - Health in serious jeopardy
 - Serious impairment of bodily function
 - Pregnant woman in contractions & no time to transfer
- Must provide appropriate screening
 - A hospital must provide the same screening to all patients who present w/ the same symptoms
- A hospital must have actual knowledge that an emergency medical condition exists.
 - If there is no knowledge → There is no liability under EMTALA
 - But if the screening is so low that it causes the hospital not to have actual knowledge → EMTALA violation

- **2. Duty to Stabilize**

- If hospital admits the patient → The duty is satisfied under EMTALA
 - However, for pregnant women in labor → Pt not stabilized until baby is delivered
- Hospital may not delay screening to find out if they have insurance !!!
- **Certain times a patient can be transferred when they have an unstable condition**
 - Upon patient request that is in writing after the hospital has informed them of the risks of transfer
 - Don't say "upon informed consent of exam", that's wrong !!!
 - Physician certifies in writing that benefits of transfer outweigh the risks
 - Transfer must be appropriate
 - To app facility
 - Receiving hospital must agree to accept
 - Transferring hospital must send the ER records
 - Transfer must be by appropriate means

- **3. Enforcement**

- ...see *handout*
- A patient can sue a hospital for DAS for violating EMTALA. They may not sue the physician under EMTALA (but can under medical malpractice)

- **4. Transfer**

PROBLEM: EMTALA AND HHS REGULATION

EMTALA applies only to hospitals that accept payment from Medicare and have an emergency department. Under EMTALA, a hospital has a duty to screen. A hospital must provide the same screening to all patients who present w/ the same symptoms. A hospital must screen a patient if an *emergency medical condition* exists. An *emergency medical condition* exists for a pregnant woman if she is going into contractions and the patient is not considered stabilized until the baby is delivered.

AMERICANS WITH DISABILITIES ACT (ADA)

- For most areas of life, can't discriminate on the basis of disability.
- **The exception:**

[Bragden v. Abbott](#), p326

TITLE VI CIVIL RIGHTS ACT OF 1964

Sum: Office of Civil Rights (OCR) can pursue both intentional and disparate impact cases under Title VI. Now there's no individual claims of discrimination !!!

Prohibits discrimination on the basis of race, color, or national origin by any program receiving federal financial assistance

Prohibits intentional discrimination & discrimination through facially neutral activities that have a disparate impact

Individuals can bring suit

Individuals can't bring suit

Historically Private physician practices could discriminate (barring any contractual relationship)

Today Private physician practices can't discriminate

- A policy limiting the amount of nursing home beds available to Medicaid patients is ___ will disproportionately affect blacks.
Linton, p.333

Disparate Impact Claim: COA that a race was disparately impacted

Today No private COA may be taken for a disparate impact claim

PROBLEM: THE HEALTH FAIR

PART I

The first question is does she have an emergency medical condition?

- **If yes → Was she stabilized and released?**

Here, she was properly screened and they discovered possible melanoma, but since she was stabilized and released, the hospital did not incur a duty. Even if it was an emergency medical condition, if the hospital undertook to perform a biopsy, it could cause the hospital to have a duty so hospitals are really careful about these things so that they don't incur a duty (which would cause them to have to treat her at a later date).

PART II

The first question is does she have an emergency medical condition?

- **If yes → Was she stabilized and released?**

Here, she was properly screened and they discovered possible melanoma, but since she was stabilized and released, the hospital did not incur a duty. Even if it was an emergency medical condition, if the hospital undertook to perform a biopsy, it could cause the hospital to have a duty so hospitals are really careful about these things so that they don't incur a duty (which would cause them to have to treat her at a later date).

PRIVATE HEALTH INSURANCE & MANAGED CARE REGULATION

Historically Federal law regulated only a few things

Today Federal law regulates to a much greater extent

- ACA extends federal regulation over the non-group (individual) market
- ACA applies more federal req'ts to group health insurance plans, including self-insurance plans

Healthcare & consumer markets are different b/c you might not be able to shop around for healthcare—may need care to stay alive

Remember, If employers don't provide adequate coverage → Must pay a penalty

Underwriting: Process of setting premiums

Adverse Selection: Tendency of people who are sick to want to get health insurance

Favorable Selection: Tendency of insurance companies to want to pick healthy people for their plans a.k.a., cherry-picking

Historically: Exclusions were allowed for pre-existing conditions

Today

- **Healthcare insurers can't vary their premium for**

- Health Status
- Medical Condition
- Claims experience
- Receipt of health care
- Medical history
- Genetic information
- Evidence of Insurability
- Disability

- **2 Main Exceptions:**

- Can vary their premium for age, except that it can't vary by more than 3 to 1
- Can vary their premium for tobacco use (up to 50% more)

MINIMUM ESSENTIAL BENEFIT & COST-SHARING REQUIREMENTS

Non-group Market

Individuals, families, and small groups

Group Market

Large group, employer groups

Today

- Annual limits and lifetime limits are gone
- There are some limitations on services
- No rescission of coverage except for fraud
 - E.g., when you were 3, X happened, so we're rescinding your policy
- Quality & Assurance Programs (Q&A Programs)
- For non-group market, insurance Cos must spend .80 out of every premium dollar on Q&A programs
- For large-group market, insurance Co's must spend .80 out of every premium dollar on Q&A programs
- If they don't then insurees receive a rebate
- *Something about an Internal problem and external problem ???*

PROBLEM: INSURANCE REFORMS, P. 356

1. Today, the ACA prohibits discrimination based upon pre-existing health status. Even if she lied about her pre-existing condition, the insurance company would still be prohibited from discriminating against her
2. They do not have to cover the particular drug he is taking, but they must have one drug in each category. But if that is the only drug that is medically necessary, then they'd have to offer something (I think)
3. This is an example of a grandfathered plan. The amount they can exceed it is tied to the consumer price index + 15%. They were under that. (Don't need to know how to calculate)

DISCLOSURE REQUIREMENTS

Every insurer must disclose certain info about their plans

e.g., here is a list of products and services that you may need that we cover

Original idea was for states to set up exchanges, but if the state doesn't set one up, you use the federal exchange.
TX: Doesn't have a state exchange, so here you would use the federal exchange at healthcare.gov
 You can sign up a.i.a. you aren't in prison or here illegally

EMPLOYEE RETIREMENT AND SECURITY ACT OF 1974 (ERISA)

Pages: 368-400

History: Pre-ERISA, employers didn't have to provide health insurance. Intent was to provide an incentive

Applies: To employers who have healthcare plans for their employees

Trigger: Employer pays into the plan

Doesn't Apply

- Individual Plan
- Employers who have group plans for their employees

e.g., a group rate

General

- It has nothing to do w/ Medicare or Medicaid
- ACA has changed it
 - Post-ACA the rules are the same but not Federal law applies to *everyone*—they must provide all those things
 - States still can't regulate self-insured plans

Self-Insured Plans vs. Insured Plans

Insured Plans

MCO K's w/ Employers

Insurer collects premiums

Insurer *bears the risk* (e.g., they pay costs)

Employee-Benefit Plan

Self-Funded Plan (a.k.a., self-insured plans)

More protections, they'll claim not to be bound by state law b/c they're not deemed to be an "insurance company"

e.g., STCL would have a trust

Employee-Benefit Plan

*** Any of the state laws that would regulate insurance DO NOT apply to self-funded plans ***

29 U.S.C. § 1144

Relate To Clause

29 U.S.C. § 1144(a)

Except as provided in §(b), the provisions of this subchapter & subchapter III of this chapter shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in §1003(a) of this title and not exempt under § 1003(b) of this title. [Effective 1/1/1975]

- So...Any state law that relates to an employee benefit plan is pre-empted by ERISA

Savings Clause

29 U.S.C. § 1144(2)(A)

Except as provided in subparagraph (B), nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities.

- All of the state laws that would regulate insurance do not apply to self-funded plans !!!
- So if they regulate insurance → They're not pre-empted by ERISA
- But Federal mandates still apply to everyone e.g., If you cover mastectomy, you must also cover reconstructive surgery

Deemer Clause

29 U.S.C. § (b)(2)(B)

*Neither an employee benefit plan described in §1003(a)...., which is not exempt under §1003(b) ... (other than a plan established primarily for the purpose of providing death benefits), nor any trust established under such a plan, shall be deemed to be an **insurance company** or other insurer, bank, trust company, or investment company or to be engaged in the business of insurance or banking for purposes of any law of any State purporting to regulate insurance companies, insurance Ks, banks, trust companies, or investment companies.*

ERISA IN A NUTSHELL

If it relates to an EE benefit plan → It triggers the ERISA statute

If a state law regulates insurance → It's saved from being pre-empted by ERISA, but a *self-funded* plan is not treated as an insurer, so they don't have to follow state regulation

But now many of those state law protections have become Federal law under the ACA, so now they apply to all plans

- 1.
- 2.
- 3. Gives other relief (injunction)
- *Rush Prudential*, p. 370 - State law says they must provide an independent review...Ct says it's more like a second opinion—they're determining whether something is covered by the plan & that's all
- *Aetna v. Davla*, p. 387
 - Note that if it relates to an employee benefit plan → goes to federal court, under ERISA
 - To the extent a plan enlarges upon ERISA's remedies → It's pre-empted e.g., if state law allows more DAS
 - As a coverage decision, under Federal law → Only get reimbursement. ERISA protects them from paying punitive DAS, etc
 - *Peagram*
 - When there's a mixed treatment and eligibility decision being made, then the Ct will look at it as a treatment decision.
 - e.g., when physician provides an HMO plan and wears 2 hats—one as a doctor, one as an insurer and thus is divided b/w their treatment decisions and their coverage decisions

[ABSENT Week before spring break, studying for midterm]

A.

-

B

-

C. DRUG PROGRAMS

-

D. MANAGED CARE

Eligibility Categories

Payment Systems

MSDRG: Dx Medical Groups

- Individual mandate
 - 1% or \$9500, whichever is higher. Comes out of refund

MEDICARE VS. MEDICAID

	Medicare	Medicaid
	A welfare program for the poor	An insurance program for the elderly & disabled
Paid for by....	Employment tax revenue	Paid for by jointly Fed & State by general tax revenue e.g., 50/50 States may exceed fed min. funding guidelines e.g., 60/40 States not req'd to have [it...] If they do → Must follow fed regs
		Sensitive to economics e.g., expands when up, contracts when down
It Funds...		Long-term care (220% Fed poverty level)

MEDICAID EXPANSION

- States have the option to expand Medicaid programs beyond the minimum standard mandated by the Federal gov't
- *Dept. of Health & Human Services v FL*, p. 435
 - If the states choose to do it → Must cover everyone up to 133% Federal poverty level
 - **TX**: Has chosen not to expand

Reasons a State Might Not Expand

- Political Reasons
- Cost
- Uncompensated ER Visits

Reasons a State Might Expand

- Promoting healthcare
- Preventive care would reduce uncompensated ER visits

PROBLEM: MEDICAID ELIGIBILITY, P. 441

- Stanislaus
- Peter
- Maria: Pregnant, so covered
- The children: Would need to know the families income levels to determine
- Elzbieta (grandma w/ expired visa):
 - *Most likely Scenario*: Family would keep her home and do they best they can to care for her
 - EMTALA would cover stabilization for an emergency
- *Westside Mothers*, p.
 - Whether a private π can sue the state for failing to provide state Medicaid program, considering sovereign immunity
 - Looks to whether it is a discretionary act (no)
 - Whether a private π can sue a state official (etc...)
 - Is there a private right of action? Yes, if Ct concludes the statutory section was intended to benefit plaintiffs
 - *Blessings (sp?) Test*
 - Interests not so vague that it would strain judicial comp., etc
- *Douglas*, p.
 - State Medicaid plan reduced the payments to providers

- The complaint was that the plan caused physicians not to want to accept Medicaid & quality of care drops
- Ct says the issue is still alive but you must first exhaust the administrative remedies before they'll look at it
- And also (less importantly) that Supremacy Clause not really applicable here

2 Solutions

- States can expand Medicaid coverage for children &
- Create a separate program that provides coverage for children

Can't Use chip \$ (a Fed block? Grant) for:

- Children not covered by Medicaid &
- Children not covered by Private Insurance

For Exam

!!!

- What Medicaid is
- How it's funded
- What's the eligibility
- How's it affected by the ACA expansion (case addressing the constitutionality of it)
- Is there a private action for it
- 2 points on board about CHIP Program

PROFESSIONAL RELATIONSHIPS IN HEALTH CARE ENTERPRISES

p.475-502

Averse Selection: Tenancy of People who are sick or become sick and seek medical insurance

Medicare Shared Savings Program: A hospital who meets certain benchmarks has an incentive to provide better quality of care in order to earn a larger reimbursement

Peer Review Process (a.k.a. professional review process)

- Medical staff has its own set of bylaws

See org chart

STAFF PRIVILEGES AND HOSPITAL-PHYSICIAN CONTRACTS

REVIEWING THE MERITS OF PRIVILEGES DECISIONS

State law requires that a physician must be afforded procedural due process (notice & a hearing) before a hospital may terminate their privileges.

Majority: Most states don't allow the courts to review the merits of privileges decisions

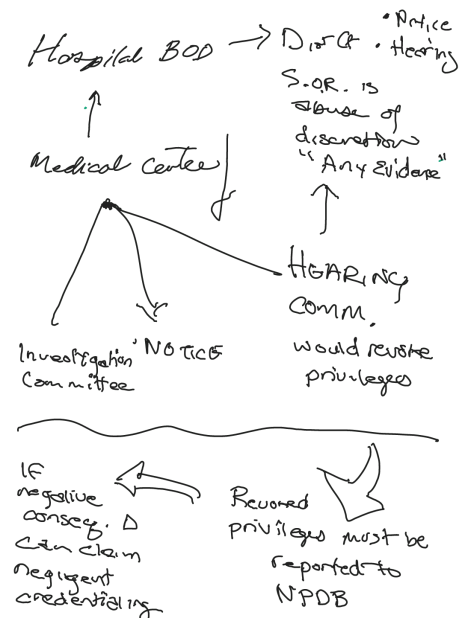
Primary Inquiry: Did the hospital follow its own rules? !!!

Minority: Minority opinion b/c allows review of the merits of privileges.

Minority looks for Abuse of Discretion, "any evidence" !!!

Minority court opinion. Bylaws say "staff member must be given notice of the decision of the Medical Council and the notice shall specify "what action was taken or proposed to be taken and the reasons for it." Looks at fundamental fairness in procedural due process for hearing to revoke medical privileges.

- Sokol v. Akron General Medical Center, p. 477



HEALTH CARE QUALITY IMPROVEMENT ACT (HCQIA)

[42 U.S.C. § 11101](#)

Overview

- Affords hospitals immunity from DAS actions, except for civil rights claims
- Creates a rebuttable presumption that the credentialing decision complies w/ the standards of the Act

To rebut the presumption, π must prove by a preponderance of the evidence:

- (1) did not act in the reasonable belief that the action was in furtherance of quality health care
- (2) did not make a reasonable effort to obtain the facts
- (3) did not afford the physician notice and hearing procedures and such other procedures req'd by fairness under the circo
- (4) did not act in such reasonable effort to determine the facts & after meeting the Act's procedural req't's

HCQIA Immunity

To earn HCQIA Immunity, hospitals must report certain adverse credentialing decisions to the NPDB

A hospital may receive procedural protections so long as termination of privileges was a business decision made to improve patient care.

Matteo-Woodburn v. Fresno Community Hospital, p. 484

- If it reflects on the physician that they're of poor character → Entitled to Medical Staff Bylaws
- If the hospital is re-structuring → Not entitled to Medical Staff Bylaws
 - ...so if a hospital is re-structuring, it does not need to provide procedural due process !!!
- **Key:** Does it reflect on the physicians character, his competency? **!!!**
- **Clean Sweep Provision:** If K terminated by hospital → Effectively terminates privileges

Economic Credentialing:

PROBLEM: P. 491-492 (DR. BENNETT)

LABOR AND EMPLOYMENT

EMPLOYMENT AT WILL

Doctrine of Employment at Will: Employment relationship can be terminated w/o cause at the will of the EE or the EM

MEDICARE & MEDICAID FRAUD AND ABUSE

OVERVIEW: THE 3 STATUTES

1. Civil False Claims Act

- Any person who knowingly presents a false claim, record, or statement, or conspires to (same) **is liable for**
 - \$5,000 - \$10,000 each claim + 3x the amount of DAS sustained by the gov't + exclusion from Medicare/Medicaid
- **knowingly, the scienter: actual knowledge, reckless disregard, deliberate ignorance*

- Qui Tam Actions

-

2. Illegal Renumeration Act (Anti-kickback statute)

3. Stark Law

- *Does the transaction involve...*

- **A physician**

- **Making a referral of a m/m patient**

- **For a designated health service (DHS)**

- Critical laboratory services
- Physical therapy services
- Occupational therapy services
- Radiology
- Radiation therapy services & supplies
- Durable Medical Equipment and Supplies

- Parenteral (intravenous feeding) and enteral nutrients(feeding)

- Prosthetics

- Home health services

- Outpatient services

- Prescription drugs

- **To an entity w/ which the physician has a financial relationship**

- Compensation

- Ownership

- Investment

CIVIL FALSE CLAIMS ACT

Exam Analysis

Any person who **knowingly** presents a false claim, record, or statement, or conspires to (same) **is liable for**

\$5,000 - \$10,000 each claim
+ **3x the amount of DAS** sustained by the gov't
+ **exclusion** from Medicare/Medicaid

**knowingly, the scienter =*
actual knowledge, reckless disregard, deliberate ignorance

Common Types

- Providers asking for reimbursement for services rendered that were not
- Falsified patients that don't exist
- Kickbacks e.g., pharmaceutical co. pays you for giving pts certain drugs
- Lack of medical necessity e.g., scooter store had dr's falsify records in order to charge for premium scooters, but sold them & provided patients (who didn't need them) a lower quality scooter
- Falsified applications or research for research grants

Top cases of recovery

- Recovery is civil fines (administrative penalties that go to the gov't)

GOVERNMENT ENFORCEMENT

- *US v. Krizek*, p. 584

QUI TAM ACTIONS

He who litigates in this matter for the king [as well as] for himself

Civil Actions for False Claims

31 U.S.C. § 3730

- A private person may bring civil action on behalf of the gov't a.k.a., whistleblower
 - Must be the **original source** w/ independent knowledge
- Complaint is filed in camera (in private), under seal for 60 days (may be extended)
 - Under seal to avoid tipping off the wrongdoer
 - Allows gov't to investigate
 - Gov't may elect to intervene & proceed w/ the case itself
 - Gov't makes all decisions (but private person remains a party)
 - Or, gov't may decline and person may still proceed
 - Relator=qui tam π (QTP)
- If gov't intervenes → relator gets 15-25% of recovery + atty fees
- If gov't doesn't intervene → relator gets 25-30% of recovery
- **Whistleblower provision**
 - EE must show
 - Engaged in activity in furtherance of qui tam suit
 - EM knew of EE's qui tam action
 - EM retaliated b/c of those actions
 - If EE wins → gets reinstatement + 2x back pay (w/ interest) + fees, costs
- Gov't K's w/ private groups to do these audits
- ACA
 - Must report to the gov't any direct or indirect payment they are given re: drugs

- There's supposed to be a website that shows what incentives must be reported

p. 603 - 621 (illegal remuneration statute)

Illegal entity that's formed. It manages the physicians practice

problem p. 604 - 605 (fraud and abuse)

problem p. 613 (recruiting Dr. Ryan)

THE STATUTE

§ 1320a-7b. Criminal penalties for acts involving Federal health care programs

42 U.S.C. § 1320A-7B

(a) Making or causing to be made false statements or representations

- Whoever--

- (1) knowingly and willfully makes or causes any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program (as defined in (f)),
-
- (2) knowingly and willfully makes or causes any false statement or representation of a material fact in determining rights to such benefit or payment
-
- (3) having knowledge of the occurrence of any event affecting...
 - (A) his initial or continued right to any such benefit or payment, or
 - (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized,
-
- (4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,
-
- (5) presents or causes to be presented a claim for a physician's service for which payment may be made under a Federal health care program and knows that the individual who furnished the service was not licensed as a physician, or
-
- (6) for a fee knowingly and willfully counsels or assists an individual to dispose of assets (including by any transfer in trust) in order for the individual to become eligible for medical assistance under a State plan under subchapter XIX of this chapter, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under §1396p(c).

- **shall**

- (i) in the case of such a statement, representation, concealment, failure, or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under the program, be guilty of a felony and fined not more than \$25,000 if convicted or max 5 years prison or both, or
- (ii) in the case of such a statement, representation, concealment, failure, conversion, or provision of counsel or assistance by any other person, be guilty of a misdemeanor and fined not more than \$10,000, if convicted or max 1 year prison, or both.
- In addition, in any case where an individual who is otherwise eligible for assistance under a Federal health care program is convicted → the administrator of the program may at its option, limit, restrict, or suspend the eligibility of that individual for such period (max 1 year; but it shall not affect the eligibility of any other person for assistance under the plan, regardless of the relationship b/w that individual and such other person.

They've violated it unless the parties meet a safe harbor

(b) Illegal remunerations

(1) whoever knowingly and willfully **SOLICITS or RECEIVES** any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

- **(A) in return for referring** an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program

OR

- **(B) in return for purchasing**, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program

(2) whoever knowingly and willfully **OFFERS or PAYS** any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind **to any person to induce such person--**

- **(A) to refer** an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program

OR

- **(B) to purchase**, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

...SHALL BE GUILTY OF A **FELONY & FINED NOT MORE THAN \$25,000** IF CONVICTED OR **MAX 5 YEARS** PRISON, OR **BOTH**.

(3) (1)&(2) shall **NOT APPLY** to—

- **(A) a discount or other reduction in price** obtained by a provider of services or other entity under a Federal health care program **IF the reduction is properly disclosed and reflected** in the costs claimed or charges made by [them]
- **(B) any amount paid by an employer to an employee** (who has a bona fide employment relationship w/ such employer) **for employment in the provision of covered items or services**

(f) Federal health care program

- **(1)** any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the gov't (other than the health insurance program under chapter 89 of Title 5) **or**
- **(2)** any State health care program, as defined in §1320a-7(h)

(h) Actual knowledge or specific intent [to commit] a violation **not required**

PROBLEMS: ADVISING UNDER THE FRAUD AND ABUSE

Whoever *knowingly*
Solicits, received, offers to pay, or pays
Any remuneration > directly, indirectly, overtly, or covertly / in cash or in kind
For patient referral >
or for purchase, lease, ordering of goods, services, items, facilities
Paid for w/ Federal Health Care \$
Has violated the statute
May be convicted of a felony
And fined up to \$25,000 **or** up to 5 years prison **or** both

Actual knowledge of this section or specific intent to violate it is not required

One Purpose Test

- If one purpose of the arrangement was to induce patient referrals → Medicare statute is violated
- **Almost every violation of the AKS statute → is almost always also a violation of the False Claims Act**

SAFE HARBOR PROVISIONS

Generally

- There are 25
- If they comply exactly w/ the safe harbor → Won't be prosecuted
- If they don't comply exactly w/ the safe harbor → May or may not be prosecuted
- All safe harbors say that the remuneration must not be based on patient referrals

Leases for Space or Rental of Equipment

- Must be in writing & signed by the parties &
 - For at least a year &
 - It must specifically identify the space &
 - Specify when and for how long the space will be used &
 - The amount in rent must be set in advance &
 - Can't take into account the amount of referrals generated &
 - FMV
- EX: We'll see how the referrals to the hospital go & maybe you'll get a discount → Violation

Personal Services or Management Contracts

- Must be in writing & signed by the parties &
- For at least a year &
- It must specify what services they must do &
- Compensation must be set in advance &
- Can't take into account the amount of referrals generated &
- FMV

~~—Sale of Practice: Seller must be a retiring physician~~

Practitioner Recruitment

Students tend to forget **penalties** and **SCIENTER**

!!!

PROBLEM P. 626 (GROUP PRACTICES)

PRACTICE PROBLEM (HANDOUT)

If they respond w/ state law like this → Respond that you're suing under Federal law, which effectively avoids its. Here, they were trying to bring *Parkway* into it and you don't need to deal w/ it.

DAS

TCPA → Can get actual DAS + atty fees + up to 3x add'l DAS under the tie-in statute
→ Maybe mental anguish

Exam Analysis !!!*Does the transaction involve...*

- A physician
- making a **referral of a Medicare or Medicaid patient**
- for a **designated health service (DHS)**...
 - Critical laboratory services
 - Physical therapy services
 - Occupational therapy services
 - Radiology
 - Radiation therapy services & supplies
 - Durable Medical Equipment and Supplies
 - Parenteral (intravenous feeding) & enteral nutrients (feeding)
 - Prosthetics
 - Home health services
 - Outpatient services
 - Prescription drugs
- ...to an **entity** w/ which the physician has a **financial relationship**
 - Compensation
 - Ownership
 - Investment

If there's a safe harbor and you meet the elements exactly → No prosecution

If you don't meet it → There may be a prosecution. If there is, they look to **intent**.

A violation of the Stark law *may* be a violation of the **False Claims Act** if inappropriate payments were made to Medicare and Medicaid.

{it doesn't work the other way around}

However, a violation of the Stark Law *may* also violate the **Anti-Kickback Statute**

a.k.a. the prohibition against self-referral

Created b/c: There was a lot of incentive for physicians to obtain their own equipment and have their patients use it. This created a problem w/ unnecessary services b/c the only way to pay for it was to have patients use it (self-referral)

TX doesn't have any Stark statute.

THE STATUTE

Limitation on certain physician referrals

42 U.S.C.A. § 1395nn

(a) Prohibition of certain referrals

- (1) In general
 - Except as provided in (b), if a physician (or their immediate family member) has a financial relationship with an entity specified in (2), then—
 - **(A)** the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter &
 - **(B)** the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, 3P payor, or other entity for designated health services furnished pursuant to a referral prohibited under (A).

DIFFERENCES B/W AKS VS. THE STARK LAW

Illegal Renumeration (Anti-Kickback Statute)

Criminal and civil penalties
Scienter req't (knowingly & willfully)
Safe Harbors/Statutory Exceptions: May be legal even if it falls outside safe harbor
Advisory opinions available from OIG – fraud alerts; advisory bulletins
Doesn't require a physician to be involved in the transaction

Max penalties:
Criminal: \$25,000 + 5 yrs
Civil: \$2,000 - \$15,000

Exclusion

Stark Law (Physician Self-Referral Statute)

Civil penalties only
No Scienter req't
Exceptions: Violated if not in strict compliance
Advisory opinions available from CMS
Requires a physician to be involved in the transaction

Max penalties:
Criminal: \$15,000 per item billed + fund of any amounts paid
Civil:

Exclusion

PROBLEM: GROUP PRACTICES

- Definition of Group Practice 42 U.S.C. § 1395nn
- They're called integrated delivery methods
- The risk is self-referral but if you do all these things it minimizes the risk
- Medical directorship is a personal services K

CONTRACEPTION, ABORTION AND STERILIZATION

When is something Human?

- Fletcher identifies the following attributes of Personhood
 - Minimum intelligence
 - Self-awareness
 - Self-Control
 - A sense of time
 - A sense of the Future
 - A sense of the Past
- Capability to relate to others
- Concern for others
- Communication
- Control of Existence
- Curiosity
- Change and changeability
- Balance of Rationality and Feeling
- Idiosyncrasy (to be recognizable, to have an identity)
- Neocortical function

CONTRACEPTION & ABORTION, P. 713-748

Roe v. Wade

Facts: Roe was unmarried & wanted an abortion. Claimed TX § was unconstitutional b/c right to privacy

Fundamental Right? Fundamental Right to abortion

Substantial Infringement? Yes

Level of Scrutiny: Strict Scrutiny

Holding: Came up w/ trimester framework (overruled) 1) Dr. Must perform; 2) Health of mother; 3) Health of baby

- No state interest in 1st trimester. Interest after 1st trimester for health of mother, viability of life – that's part and parcel of the

Hyde Amendment

- Ct determines fetus isn't a 'person'- word only applied post-natally

*A constitutionally-based right of privacy extends to personal procreative decisions.
This right is based in the DP clause of the 14th Amendment.*

The question is at what point does the states interest override a womans right to chose.

Hyde Amendment (1980)

- Federal Funds couldn't be used for virtually any abortion. There's been some back and forth over the years
- Explicitly permits state-funded Medicaid abortions

Planned Parenthood v. Casey, p.720

- 1) Informed consent → No undue burden
- 2) 24-hour waiting period (non-emergency) → No undue burden
- 3) ~~Spousal Consent~~ → Undue burden
- 4) Parental consent (w/ way to bypass) → No undue burden
- 5) ~~Stopping all partial-birth abortions (viability)~~ → Undue burden
- 6) Record-keeping → No undue burden

- **Undue Burden Test:** State may regulate abortion so long as it doesn't place a substantial obstacle in the way of a woman who chooses to have an abortion
- Reaffirms the essential holding of *Woe v. Wade*
- The current test
- Very different than the test used by *Roe v. Wade*
- State published informed consent materials must be given to a woman prior to her receiving an abortion. The physician is req'd to *tell* the woman the materials are available (and to give them to her if she requests):
 - Adoption
 - Support for having a child
 - Child Support
 - Etc
- 24-hour waiting period

Partial-Birth Abortion

Gonzalez v. Carhart, p. 732

- Upholds the Partial Birth Abortion Ban Act of 2003
- When some part of the baby is outside of the mother

TX:

- Physician performing an abortion must have staff privileges nearby are w/in 30 miles
 - DistCt said it was unconstitutional b/c it was an undue burden
 - Will be up before the SupCt

PROBLEM: STATE ABORTION LAWS P. 758 - 760

CHAPTER 16: LIFE AND DEATH DECISIONS

P. 767–778

Cruzan

Principles

- 1 Respect for Autonomy
 - Grows out from Nuremberg Trials b/c of medical experiments. Result was the Nuremberg code which started with voluntary
 - In order for a decision to be voluntary, it must be autonomous
- 2 Beneficence
 - 'Do no harm'
 - Often applied in the standard that the benefits of a treatment must outweigh the risk
- 3 Justice
 - *Cruzan v. Director, Missouri Dept. of Health*, p.767
 - Parents seek court order directing their daughter to be removed from life support following an automobile accident that rendered her brain-dead
 - State interest in preserving life
 - 14th Amendment provides that no State shall "deprive any person of life liberty, or property, without due process of law."
 - The principle is that a person has a constitutionally protected liberty interest in refusing medical treatment

PROBLEM: CHRISTIAN SCIENTIST IN THE ER P. 785

When an individual is competent and has the capacity to make informed decisions, the state interest in preserving life is outweighed. The patient must have been informed of the risks of their decision and understand the consequences that could occur should they choose to refuse treatment. The state cannot intervene with her decision solely on the basis of preserving life. There is also an issue of freedom of religion

Order of Decision-Making Power

- Power of Attorney, then advanced directives, then this:
 - Statute regarding order of medical decisions: Spouse, then children, then child siblings have decided to speak for all, then majority of those children, then parents **not on exam**
 - This statutory decision-making guidelines do not come into play unless there is not power of attorney or advanced directives

ADULTS WITH DECISION-MAKING CAPACITY P. 785-800

A hospitals process if the physicians disagree w/ a family that wants a patient kept alive when intensive or continual care is needed

Phase I

Phase II

Phase III - ? resolution – when they may try to transfer the patient

Then if that doesn't work, legal council will come in and they'll try to get a Ct order.

FUTILE TREATMENT, P. 853-863

TX FUTILITY STATUTE

**Statements' Explaining Patients Right to Transfer
Registry to Assist Transfers**

**TX Health and Safety Code § 166.046
TX Health and Safety Code § 166.052
TX Health and Safety Code § 166.053**

Use of the term "futile"

p.856

- Treatment has no chance of achieving the desired physiological effect
- Treatment extremely unlikely to achieve its immediate goals
- Treatment may achieve immediate physiological goals but would fail to achieve long-term goals or cause patient to undergo continual or repeated interventions over a very short time prior to death
- Harm caused by treatment outweighs benefit

- Cost grossly disproportionate to the expected benefit

Should never be the primary factor

TX: After review, if you still request life support but the physicians disagree

p.856, TX policy only !!!

- Physician, w/ hospitals help, will search for somewhere willing to provide the requested treatment
- The list of places that will do it is given to you
- Life support continued up to 10 days from the time the list is received
 - If can't find an acceptor w/in 10 days → May w/draw life support unless Ct grants extension
 - If acceptance & transfer will occur → Patient responsible for transfer costs
- If the patient is taken home and then something happens causing them to return to the hospital, then they can provide no treatment
-

PROBLEM: WITH WHICH POLICY DO YOU AGREE? (TEXAS STATUTE, CHRISTUS ST. VINCENT, OR FROEDHERT HOSPITAL)

CHAPTER 17: MEDICALLY ASSISTED DYING

Voluntary Euthanasia

- Where someone directly assists in the death
- Not accepted by any states

Medically-Assisted *Death* (formerly *Physician-Assisted Suicide*, then *Physician-Assisted Death*)

CONSTITUTIONAL FRAMEWORK, P 865-882

- DP liberty interest is a fundamental right

“No person shall be denied life, liberty, or property w/o due process of law”

-

Oregon Death with Dignity Act p.886-903

There must be a determination that someone is terminally ill...

Requirements

- Must be terminal &
- Competent &
- A Resident &
- Voluntary (which includes)
 - Informed
 - Whats the diagnosis?
 - Whats the prognosis
 - What are the risks?
 - What alternatives?
- Must be an oral request
- A written request + 2 W's &
- 15 day waiting period & then
- 2nd oral request & then
- an opportunity to rescind
- ...at which point the physician

e.g., palliative care

FINAL EXAM REVIEW

Exam Overview

- 180 minutes, 3 hour exam
- 55 MC questions worth 2 points each. Dedicate approximately 2 hours to them
- 2 essays, Dedicate 1 hour to them

Regulation of Quality of Care

- **Who regulates?**
 - 1. Medical Board
 - Functions of the Medical Board
 - Governs the licensing process
 - Governs the disciplinary process
 - Appeals are made through the state district court and on up through the appellate system
 - 2. National Practitioners Data Bank (NPDB)
 - **To check:** Board will check the NPDB when apply for license and other occasions where there's a disciplinary action
 - **To report:** People must report disciplinary actions for physicians
 - DEA reports adverse actions
 - Medicaid reports exclusions
 - Insurance companies report malpractice claims
 - JCAO – important for hospitals b/c if they have deemed status its important for their Medicaid
- **Practice of Medicine**
 - Must have a license to diagnose, treat, or to publicly hold oneself out as a physician, otherwise they are practicing medicine w/o a license
- **Delegation**
 - Can.... Any person
 - New prescriptive authority agreement (PAA) is a written agreement b/w physician and APN or PA
 - The physician can delegate specific categories of drugs w/ far less review than was previously req'd
- **Nursing Home Regulation**
 - Layers of Federal law over nursing homes
 - USC
 - Admin Regulations
 - Agency Rules & Guidelines
 - 3 phases of Nursing Home Regulation
 - Survey Phase Where they answer questions about how they manage QOC
 - Inspections Phase Where surveyors come around
 - Sanctions Phase
 - If warranted
 - Case where fed secretary for health and human services has a duty to ensure that ...and ensure that its providing ...care
 - ?
- **Chapter 3 Professional-Patient Relationship**
 - A physician retained by workers comp exam alone does not create a physician-patient relationship
 - **Contractual**
 - It may be K'I where if physician has an agreement with a managed care organization, for example an HMO
 - Or physician works in the emergency room
 - Exculpatory Clauses
 - **Partial limitation on the right to sue**
 - Those are recognized
 - w/ respect to liability and tort DAS the comparative fault could be a portion, like in the Jehovahs W case
 - **Informed Consent**
 - A physician bears ultimate legal responsibility for getting consent from the patient
 - TX its statutory....
 - See list A and list B.
 - There's certain rebuttable pres.
 - And if not on either it's the CL standard: that's on the handout
- **Confidential Disclosure of Medical Information**

- There can be tort liability for disclosure of confidential medical information
 - In TX of course that would be a healthcare liability claim
- HIPPA 86
 - Handout says everything
 - Whom does it apply? Protect?
 - Required disclosures?
 - Usually when an individual asks for their own information
 - What disclosures are permitted?
 - Everything else needs an authorization
 - **Minimum Standard**
 - ...civil rights but not a private COA
- Liability of Healthcare Professionals
 - SOC for physicians is the national SOC
 - The community SOC is ...to the extent that it reflects what the National SOC would be
- Expert testimony and the qualifications Experts
 - CPRC Chapter 74
 - CPRC Chapter 4
 - Experts must be practicing medicine at the time the claim arose
 - They don't have to be board certified in their specialty, although it is best that they are. They can testify as long as they're an expert as to what they testify about.
 - National SOC
 - Expert report in a lawsuit and the CV of the expert must be filed w/in 120 days after the date at which the Δ s original answer is file (it used to be from the π s petition)
 - SOL in TX
 - 2 years
 - The traditional discovery rule is not honored in TX. The π must have a reason time in which to file suit
 - So if ...after the sponge was left....still leaves 6 months
 - Has a 10 yrs statute of repose ---a complete cutoff of claims
 -DAS
 - π s can't recover if their responsibility is <50% (a.k.a. the 51 percent bar rule)
 - TX in minority on last chance doctrine
 - a π s chance of survival must be 51% at the time the cancer is diagnosed or should have been diagnosed
 - The courts have look at it: Physicians negligence must be a substantial factor in causing the death if the π had an 80% chance of dying anyway at the time

Chapter 5 Liability of Healthcare Institutions

- Agency law and respondeat superior
 - A hospital is responsible for the negligent acts of of its EEs
 - Π can sue the hospital and its employees.
 - They can both be sued
 - The inquiry w/ respect to agency law is whether the hospital has the right to control the details of the work
- **The Borrowed Servant Exception**
 - A physician may be liable for the acts of a hospital employee if they delegate something to the nurse that...
 - The general rule is that physicians are independent contractors. Hospitals are generally not liable for the acts of its physicians b/c they're usually independent contractors, not employees.
- Apparent authority
 - Often applied to hospital-based physicians
 - Pathology, radiology
 - Rules: Is the hospital affirmatively holding out the physician as its agent?
 - 1st requirement is
 - 2nd requirement is justifiable reliance by 3p which is the patient
 - A hospital would defend by saying they had signed disclaimers or that there were signs up that show they didn't appear to be EEs
- Hospitals can be liable for ordinary negligent
 - Case: policy was to discharge psychiati...
 - H must have a duty to use ordinary care, such as in admitting or discharging.
- Corporate negligence
 - Duty to use reasonable care.....safe and adequate facilities
 - Proof of SOC for a hispital is the national standard of care
 - Medicare/Medicaid
 - Hospitals own bylaws
 - Board of directors has ultimately responsibility but that's generally...to the medical staff committee

- Not subject to discovery in a civil trial
- That committee has immunity under HIQUIA
 - Part of that duty in good faith is to check the NPDB. If they don't do that they are not immune.
 - Duty to not discriminate on the basis of race
 - In order to have immunity the hospital must act w/ objective reasonableness and w/o malice.
 - They would have to show that the credentialing committee acted with malice.
 - So for that reason we don't really have any cases based on negligent credentialing in TX
 - No duty to provide correct negative information
- Managed Care Organizations
 - The duty to ...also applies to MCO's
 - Gatekeepers
 - Need a referral to a specialist
 - Utilization Review Process
 - Can lead to some liability under the Thompson Duties
- PPOs
 - People who are insured under a PPO
 - The opposite is a pure HMO form where they are only covered inside the network

Chapter 7 Healthcare Costs and Access

- How did people receive their healthcare up until the ACA
-

In the individual and small group market, premiums may be based up:

- Geographic area
- Age
- Tobacco use

Wellness programs

Can get discounts for having it but not on exam

- Exchanges
 - Some states chose to run their own exchanges
 - If you don't have a group health plan thru and EM, then you can go to the exchange
 - Federal subsidy will help people but must go thru the exchange to get the subsidy
- ERISA
 - A federal statute that regulates employer benefit plans
 - Handout
 - If law relates to employer benefit (e.g., u must do X) then its preempted by ERISA unless it is the regulation of insurance in which case its saved by pre-emption
 - Makes a distinction b/w 2 types of plans
 - Insured Plan
 - EMR self Funder (or self insured plan)
 - Where EMR establishes a trust fund and pays for all the claims
 - Main diff is that EMR self funded doesn't have to...
 - Both plans are ERISA plans
 - Prevents certain tort claims
 - Case sued under state law for not coverage of a medication
 - Ct said no tort DAS under ERISA
 - You've already paid to have the benefit
- Medicare
 - Eligibility
 - Eligible at 65
 - Disabled + Eligible for social security
 - ALS
 - ESRD
 - Original....
 - Part A
 - H, home health, skilled nursing, hospice
 - Some cost sharing. H must pay deductibles
 - Part B
 - Primarily for physicians services
 - Must purchase

- Some cost sharing
 - Typically under Medicare its 20% co-insurance
- Supplemental private policy that covers the gaps that Medicare doesn't fill
 - Part D
 - Drug plan
 - Private plan again, must purchase from private co and covers the drug
- Medicare advantage plan
 - MC plan
 - Hospital services dr services, drugs, all wrapped up in it
 - So not 1 thing u pay premiums for
 - Limited to a particular network (vs MC plan)
- Prospective Payment System
 - Prices set in advance
 - MS DRG
 - DRG
 - x related groups
 - # that reflects a certain dx category
 - # weighted to reflect the resources consumed by that category as compared with the average patient, disease costs
 - other adjustments made
 - MS
 - Recognizes you get more \$ for...
- Medicaid
 - F/S comprehensive program for the deserving poor
 - Paid for out of general tax revenue
 - Constitutional challenge to ACAs Medicaid expansion (everyone must cover up to 133% fed poverty level)
 - Became voluntary b/c they
 - TX didn't expand
 - Traditional Medicaid covers babies, ? pregnant women
 - Leaves out all adults who aren't pregnant, not old
 - Cost for states that did expand
 - Fed subsidized
- Chapter 11 Professional Relationships
 - H has bylaws and medical staff does to (so two in al)
 - Medical staff bylaws
 - Procedural protects for staff docs whenever ...modified or
 - H has.....to the exclusion of all others
 - *Mateo-Woodburn* case
 - Procedural protections r not triggered unless the ...iw not triggering it individually
 - Byt ???
 - Not covered by procedural protections
- Chapter 13 Fraud and Abuse
 - Civil false claims act
 - *Crezak* case: upcoding case
 - Any person who knowingly....
 - 5-10K adjusted per claim + 3x DAS sustained by the gov't
 - SCIENTER req't
 - actual knowledge...reckless ignorance
 - QUI TAM suits
 - Brought by original source
 - Relator gets 15-25% of recovery (they're the p)
 - If they take it to ct on their own, then they get 25-30%
 - Gov't audit program
 - Being done by private Kor's
 - Corp Integrity Agreements
 - Corps agree to do reporting and education in return to keep their certification
 - Anti-Kickback Statute
 - Def
 - Criminal statute
 - Felony 25K 5 years or both
 - Administrative penalties

- Unless safe harbor
 - Recognize the reqt's
- Stark law
 - Applies to transactions that involve a physician making a referral of a M or M patient for a designated health service to an entity in while the physician has a....or an immediate family member
 - Penalty
 - Pay any amount billed while in violation must go to gov't
 - Fine 15000 per item build
 - See handout comparing illegal remuneration
 - Liability
 - Liable unless 35 exceptions
 - They're similar to the AKS exceptions
 - But with stark the services must be reasonable
 - Exception
 - Biggest exception was the org of a group practice so they could ancillary services
 - Not on exam
- Bioethics
 - Contraception and abortion
 - Undue burden test
 - *Planned Parenthood v Casey*
 - Partial birth abortion in *Gonzales*
 - Not unconstitutional b/c there would be other choices
 - Life & death decisions
 - *Cruzan*: req's c&c evidence to w/draw life support (higher burden, constitutional)
 - But some judges said const. right to resist medical treatment
 - TX
 - Looks to
 - Looks to advanced directions
 - Then power of atty
 - Then statutory line up
 - ____ statute will control see *Sun-Hudson*
- Medically assisted death
 - OR death w/ dignity act
 - They only describe the dose
 - 2 written + 1 oral request
 - **Review is at: !!!** <http://stream.stcl.edu>
 -

EXAM TIPS

Room: 4009, Library, 4th Floor, in the corner

Contact Info:

Exam Format: Multiple Choice and Short Essay

Do:

Don't:

Activities: Health Law Society @ STCL

- Exam review will have a focus section on the ACA
- All she expects is that we grasp the heart of the concepts
 - EMTALA, ERISA, fraud statutes, False Claims Act (the big ones)
 - Medical staff bylaws that set forth procedural protections (notice + hearing) when their privileges are terminated
 - The exception is that a hospital doesn't have to when it's restructuring, so the **rule** is that you don't have to give notice and a hearing unless there's some reflection on the physicians character
- Each class has a core concept
- 4 parts
- Approx 50 MC: 4 choices, will give example on review. She likes to give 4 options and then you choose from 4 answers e.g., 1 and 4
- Mostly essay. 1 or 2 essays or short answer.