American College of Healthcare Executives
for leaders who care

FACHE®
Fellow of the American College of Healthcare Executives

Becoming Board Certified in Healthcare Management and a Fellow of the American College of Healthcare Executives

Knowledge Area Covered in the Board of Governors Exam:

Laws and Regulations

ACHE - SouthEastTexasChapter
An Independent Chapter of the American College of Healthcare Executives

Why do we have laws?

- Protect Patients
- Enhance Quality
- Prevent Fraud and Waste
- Facilitate Commerce
- Protect Workers
- Help the Community

Patient Protection Laws

- EMTALA
- Privacy (HIPAA)
- Malpractice
- Informed Consent
- Advance Directives

EMTALA – General Rule

Any individual who (1) comes to the emergency department and (2) requests an examination or treatment for a medical condition, or on whose behalf a request is made, must

- receive an appropriate medical screening examination within the capability of the emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists, without any delay attributable to economic reasons.

Emergency Care

- Federal law: EMTALA requires
  - Medical screening examination
    - Within the capability of the hospital
    - To anyone on hospital property seeking medical care,
    - To determine if an emergency medical condition exists,
    - Regardless of thee individual's ability to pay; and
  - Stabilize any emergency medical condition or transfer an unstable patient pursuant to a request by the patient, or risk/benefit analysis, with certification.

About the Emergency Dept.

- Presents to the “dedicated emergency department,” which is defined as: any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:

1) Licensed by the state as an emergency department;
2) Held out to the public as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; OR
3) Provided at least one-third of its outpatient visits for the preceding calendar year on an urgent basis without requiring a previously scheduled appointment.

- Physically present elsewhere on hospital property, outside of the dedicated emergency room, in an attempt to gain access to the hospital for emergency care.

Medical Records

- Necessary for treatment.
- The creation of medical records is a duty of providers.
- The maintenance of medical records is a duty of providers.
- Once medical records are created, a major issue becomes how, when, and to whom they can be disclosed.

Documentation Issues

- CMS, TDSHS, and TJC all require that medical record entries be timely, accurate, legible and complete.
- Purpose:
  - ✓Identify the patient,
  - ✓Support the diagnosis,
  - ✓Justify the treatment,
  - ✓Document the course and results,
  - ✓Promote continuity of care among health care providers.

Additional Issues with Medical Records.

- Fees;
- Retention;
- Deadline;
- Liability:
- Spoliation.

HIPAA

- Federal law: HIPAA general rule:
  A covered entity cannot use or disclose protected health information unless permitted or required by the rule.

- State laws: Medical Practice Act, Hospital Licensing law, and state HIPAA.

HIPAA definitions

- Applies to “covered entities.” Healthcare providers are “covered entities”.
- Applies to “protected health information.”
- Can use information for treatment, payment, or health care operations.
  - Health care operations include QA/PI, peer review, premium rating (malpractice insurance), legal services, auditing, business planning and development, complaint resolution.

HIPAA rules

- Provide notice of privacy practices
- Allow patient to request amendment of records
- Allow patient to request accounting of releases of information.
- Allow patients to complain
- Allow patients to seek restriction of access to information.

HIPAA rules

- More restrictions on use of information for *research purposes*.
- More restrictions on use of information for marketing purposes.
- Requires written agreements with *business associates.*

HIPAA Security

- Must take reasonable actions to protect electronic health information.
- Must notify if disclosed "unsecured" health information.
- FTC "Red Flag Rules": requires that organizations have "reasonable policies and procedures in place" to identify, detect and respond to identity theft

Negligence/Malpractice

- **A Health Care Provider is Liable for Malpractice when**:
  - Has a *duty* to a patient (follow established professional standards when providing patient care)
  - *Breach* of that Duty
  - *Caused* Injury to the patient.
  - *Damages* (Money) is an adequate remedy for that Injury
- **Malpractice**: Breach of the duty to follow standard of care

Tort Reform

- Significantly reduced amount of damages for "*non*-economic damages"
  - Economic Damages – actual out-of-pocket medical expenses, lost wages
    - Not "full billed" charges (and cannot include amounts paid by insurance)
    - Lost wages cannot be speculative (e.g., "I was going to go to law school and make a lot of money.")
  - *Non*-economic Damages – pain and suffering, loss of consortium
    - $250,000 limits

Other Immunities

- Volunteer: a *volunteer of a charitable organization* is immune from civil liability for any act or omission resulting in death, damage, or injury if the volunteer was acting in the course and scope of the volunteer's duties or functions, including as an officer, director, or trustee within the organization. Sec. 84.004, Tex. Civ P & Rem Code

Other Immunities

- Good Samaritan:
- (a) A person who in good faith administers emergency care is not liable in civil damages for an act performed during the emergency *unless* the act is wilfully or wantonly negligent, including a person who:
- (1) administers emergency care using an *automated external defibrillator*; or
- (2) administers emergency care as a volunteer who is a *first responder* as the term is defined under Section 421.095, Government Code .
- (b) This section does not apply to care administered:
- (1) for or in *expectation of remuneration*, provided that being legally entitled to receive remuneration for the emergency care rendered shall not determine whether or not the care was administered for or in anticipation of remuneration; or
- (2) by a person who was at the scene of the emergency because he or a person he represents as an agent was soliciting business or seeking to perform a service for remuneration.
- Texas Civil Practice and Remedies Code § 74.151. Liability for Emergency Care

Advance Directives.

- Federal law: Patient Self-Determination Act
  - Give adult individuals, at the time of inpatient admission or enrollment, certain information about their rights under state laws governing advance directives
    - the right to participate in and direct their own health care decisions;
    - the right to accept or refuse medical or surgical treatment;
    - the right to prepare an advance directive;
    - information on the provider's policies that govern the utilization of these rights.
  - Applies to hospitals, nursing homes, hospice programs, home health agencies, and HMO's
- State Law: Advance Directives Act
  - Texas Health & Safety Code Ch. 166

Advance Directive Defined

- An instruction to administer, withhold, or withdraw life-sustaining treatment in the event of a terminal or irreversible condition.

There are four types of advanced directives:

- Directive to Physician
- Out-of-Hospital DNR Order
- Medical Power of Attorney
- DNR Orders (In hospital DNR orders)

Directive to Physician

- Tex Health & Safety Code § 166.031 – 166.053.
- Instruction to administer, withhold, or withdraw life-sustaining treatment in the event of a terminal or irreversible condition. Sec. 166.031 (1)
- Patient must be diagnosed and certified in writing as having a terminal or irreversible condition. Sec. 166.031 (2)
- Written by competent adult and signed in presence of two witnesses. Sec. 166.032 (b)
- Declarant may designate person to make health care or treatment decisions if becomes incompetent or mentally or physically incapable. Sec. 166.032 (c)

Out of Hospital DNR

- Tex Health & Safety Code § 166.081- 166.102
- Order instructs that patient should not be resuscitated by CPR, advance airway management, artificial ventilation, defibrillation, transcutaneous cardiac pacing or any other life-sustaining treatment
- patient can sign own OOH DNR
- sign in presence of two witnesses or notary
- must also be signed by physician
- effective in long-term care facilities, in-patient hospice facilities, private homes, hospital or stand-alone outpatient or emergency departments, physician's offices, or vehicles during transport
- not in patient hospital areas
- some patients wear a DNR Identification device
- can be revoked in writing or orally
- not honored if pregnant
- only in conjunction with natural process of dying

Medical Power of Attorney

- Tex Health & Safety Code § 166.151-166.166
- an agent to make your medical decisions for you
- when you are incapacitated, certified by physician
- the agent cannot commit you to inpatient mental health services, convulsive treatment,
- consent to psychotherapy or an abortion,
- or neglect you by omitting needed care
- the agent is tasked with mimicking the decision patient would have made
- Medical POA has to be in writing
- Form at section 166.164
- sign the Medical POA in presence of a notary or two witnesses

In Hospital DNR Order

- The order must be dated and issued by the patient's Attending Physician AND…

1. comply with a competent patient's written and dated directions;

2. comply with a competent patient's oral directions;
   a. delivered to or observed by two competent adult witnesses

In Hospital DNR Order

3. be issued pursuant to the patient's directions set forth in a properly executed statutory advance directive (Ch. 166, Subchapter B);
    - Signed by a notary or 2 witnesses

4. Comply with an advance directive validly executed in another state or jurisdiction (Sec. 166.005);

In Hospital DNR Order

5. be issued pursuant to the directions of a patient's legal guardian or an agent who has been granted medical power of attorney over the patient;

6. be issued pursuant to a directive issued for a patient younger than 18 years of age (Sec. 166.035);

In Hospital DNR Order

7. be issued pursuant to a nonwritten directive of a competent adult qualified patient;
   - May be non-verbal (e.g., thumbs-up, blinking, etc.)
   - In presence of 2 witnesses *and* Attending Physician

In Hospital DNR Order

8. be issued pursuant to a treatment decision under the procedures for when a person has not executed or issued a directive and is incompetent or incapable of communication (Sec. 166.039); or
   - Step-down decision-maker priority:
     - Legal Guardian
     - MPOA
     - Spouse
     - Reasonably Available Adult Children
     - Parents
     - Concurrence w/ 2nd, non-treating physician
   - If known, base decision on patient's desire

Limitations on Designated Agent

Agent cannot consent to on behalf of the principal:

- voluntary inpatient mental health services,
- convulsive treatment,
- psychosurgery,
- abortion, and
- neglect of the principal through the omission of care.

Informed Consent (Express and Implied)

- General Rule: Risks that must be disclosed are those that would influence a reasonable person. (Objective standard)

- Texas Medical Disclosure Panel
  - List A, Procedures Requiring Full Disclosure of specific risks and hazards
  - List B, Procedures Requiring No Disclosure of specific risks and hazards

Express Consent

- Consent to a List A procedure is effective if:
  - ✓in writing
  - ✓signed by patient (or person authorized)
  - ✓signed by a competent witness and
  - ✓ consent specifically states the risks and hazards in the form and degree required by the Texas Medical Disclosure Panel.

Express Consent (con't)

- If List A risks and hazards not documented as required, rebuttable presumption exists that the physician was negligent in failing to obtain informed consent.
- While nurses frequently assist in obtaining consent, several appellate courts have held that a duty to obtain informed consent is the duty of the treating physician, not the hospital. *Boney v. Mother Frances Hosp.*, 880 S.W.2d 140 (Tex. App. – Tyler 1994, writ denied); *Ritter v. Delaney*, 790 S.W.2d 29 (Tex. App. San Antonio 1990, writ denied).

Negligent Failure to Obtain Express Informed Consent

- The risk is inherent in the medical treatment or procedure performed and is a risk that could *influence a reasonable person into making a decision* whether to give or withhold consent
- Physician *failed* to disclose the risk
- Failure to disclose was *negligent*
- A *reasonable person would not have submitted* to the treatment if the person was aware that the risk was one of its perils
- The failure to obtain informed consent was a *cause* of plaintiff's damages.

Implied Consent

- Consent for care is *implied by law* when immediate treatment is required to preserve life or to prevent serious impairment of bodily functions and it is impossible to obtain the consent of the patient, his/her legal guardian, or next-of-kin.
- In such emergency situations, the physician should consult, whenever possible, with the patient's attending physician or with another physician faculty member about the existence of an emergency. This must be noted in the patient's medical record, together with statements by each physician that the emergency treatment was necessary for the reasons specified. These notations should clearly identify the nature of the threat to life or health, its immediacy, and its magnitude.

Informed Refusal

- Describe treatment or procedure
- Identify reasons treatment has been offered
- Identify potential benefits
- Note patient has been told of risks of not accepting the treatment
- Clearly document the patient has unequivocally and without condition, declined the treatment
- Identify why the patient refused, particularly if decision was rational

Capacity/Competency

- A patient must be competent in order to give *informed* consent.
- If patient is not competent, consent must be obtained from a surrogate decision maker.
- The ability, based on reasonable medical judgment, to understand and appreciate the nature and consequences of a treatment decision, including:
  - significant benefits and harms of, and
  - reasonable alternatives to a proposed treatment decision.

Incapacitated Adult

- Spouse;
- Adult child (with the waiver and consent of all other qualified adult children);
- Majority of reasonably available adult children;
- Parents;
- Nearest living relative;
- Identified medical decision maker; or
- Clergy.

Child

- Parent or guardian
- If not available (Family Code Ch. 32):
  - A grandparent;
  - An adult brother or sister;
  - An adult aunt or uncle;
  - An educational institution with written authorization;
  - Adult with care, control, and possession of the child and has written authorization;
  - Court; or
  - Peace officer with lawful custody of a minor.

Consent by Child

- Military;
- 16 years old; resides separate and apart and managing own affairs;
- Treatment for reportable infections, contagious, or communicable disease;
- Unmarried and pregnant and treatment relates to pregnancy (not abortion);
- Exam and treatment for drug or chemical addiction or use; or
- Treatment for minor's biological child if unmarried and has actual custody of the child.

Laws to Enhance Quality (and communications)

- PSQIA–the Patient Safety and Quality Improvement Act of 2005 (**PSQIA**) establishes a voluntary reporting system designed to enhance the data available to assess and resolve patient safety and health care quality issues.
- Safe Medical Device Act
- Licensing Laws
- Corporate Practice of Medicine
- Peer Review and HCQIA

PSQIA of 2005.

- Establishes Patient Safety Organizations (PSOs) to which providers (individuals and entities) can voluntarily report medical errors and patient safety information (known as “patient safety work product” or PSWP”).
- PSO will collect and analyze patient PSWP(Center for Patient Safety) and disseminate information to improve patient safety.
- Inoperable until final regulations are issued by HHS.

Safe Medical Device Act

- Requires medical device user facilities to report to the Secretary of Health and Human Services, the manufacturer, or both whenever they believe there is a probability that a medical device has caused or contributed to a death, illness, or injury.
- Defines a medical "device user facility" (DUF) to mean a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office

Licensing Laws

- Awarded a “provider number" by Medicare/Medicaid
- Licensure by the State

  Power to license pursuant to the State’s “police power” and necessary to protect the public.
  - ✓Right to practice within the scope of the license.
  - ✓The right to practice cannot be taken away without due process.
  - ✓Right to advertise, form provider/patient relationships, contract with insurance companies and apply for medical staff membership and clinical privileges at a facility.

Providers subject to licensure

- Hospitals
- Nursing Homes
- Ambulatory Surgery Centers
- Assisted Living Facilities
- Pharmacies
- ESRDs
- Physicians
- Nurses
- Optometrists
- Chiropractors
- Podiatrists
- Surgery Assistants
- Acupuncturists
- Pharmacists
- Physical Therapists
- Occupational Therapists
- Mental Health

Accredition

- Can obtain "deemed status" if meet accreditation standards– Deemed status is given by Centers for Medicare and Medicaid Services (CMS) and affirms that a national healthcare accreditation organization not only meets but exceeds expectations for a particular area of expertise in the accreditation realm.
- Accrediting bodies:
  - TJC: The Joint Commission
  - AAAHC: Accreditation Association of Ambulatory Health Care
  - ACR: American College of Radiology at www.acr.org/s_acr/index.asp
  - NCQA: National Council for Quality Assurance at www.ncqa.org

Corporate Practice of Medicine

- legal doctrine, which generally prohibits corporations, entities or individuals (i.e. non-physicians) from practicing medicine
- Public Policy – do not want non-physicians controlling physician's practice.
  - These entities may put their own financial best interest ahead of the patient's best medical interest.

Corporate Practice of Medicine

- Prohibits physicians from entering into partnerships, employee relationships, fee splitting, or other situations with non-physicians where the physician's practice of medicine is in any way controlled or directed by, or fees shared with a non-physician.
- One exception – 501(a) organizations, certified by the Texas Medical Board.

  Chapter **162.001(b) and 162.001 (c)** of the Texas Occupations Code
  - Must reserve powers to physicians.

Peer Review

- Privileging/Credentialing at facilities pursuant to laws, regulations, accreditation standards, and facility bylaws/rules & regulations/credentialing manual.
- Burden of proving competent to practice the clinical privileges requested is on the physician.
- A facility is immune for credentialing decisions unless the recommendation to credential a provider was made "*with malice*."
- Once awarded medical staff membership and clinical privileges, a physician is *entitled to due process* before they can be taken away.

Privileging and Credentialing

- Hospitals and other organizations require focused professional performance evaluations and ongoing professional performance evaluations of their medical staff
- Health Care Quality Improvement Act
  - ✓Purpose: To restrict the movement of incompetent physicians state to state without disclosure by permitting effective peer review and providing immunity for peer review participants.

Peer Review.

- Federal Laws: HCQIA and PSQIA
  - Immunity – not liable for damages

- State Laws:
  - Confidential and Privileged

HCQIA Immunity

- Reasonable belief that the action was in furtherance of healthcare;
- Reasonable effort to obtain the facts of the matter;
- Adequate notice and hearing procedures; and
- Reasonable belief that the action was warranted by the facts known.

State Laws: 2 Committees.

- Texas Health & Safety Code
  - "Medical Committee" at Chapter 161.031
- Texas Medical Practice Act
  - Medical Peer Review Committee" at Texas Occupations Code Section 160.007.

State Laws: Privileged Documents.

- Minutes
- Records and proceedings
- Communications to committee
- Waived by voluntary disclosure

CMS Never Events

- The list of preventable HACs (Hospital Acquired Conditions) is outlined in CMS' Inpatient Perspective Payment System (IPPS) FY 2009 Final Rule and includes the following 11 categories:
- ✓ foreign object retained after surgery;
- ✓ air embolism;
- ✓ blood incompatibility;
- ✓ pressure ulcers, stages III and IV;
- ✓ falls and trauma;
- ✓ catheter associated urinary infection;
- ✓ vascular catheter associated infection;
- ✓ manifestations of poor glycemic control;
- ✓ surgical site infection, mediastinitis following coronary artery bypass graft;
- ✓ surgical site infection following certain orthopedic procedures and bariatric surgery; and
- ✓ deep vein thrombosis and pulmonary embolism following certain orthopedic procedures.

Laws to Prevent Fraud and Waste

- Certificate of Need
- Stark
- Anti-Kickback

Certificate of Need (CON) laws

- Requires state government approval prior to opening or expanding a facility
- 1970s – governmental reimbursement was on a cost-plus basis – CON laws were designed to prevent duplication of costs.
- Cost-plus reimbursement has been replaced, but 34 states still have CON laws. (*Texas does not*.)

Federal Anti-Kickback Statute

- Establishes criminal penalties for any person who knowingly and willfully offers, pays, solicits, or receives any remuneration to induce, or in return for:
  - ✓Referring an individual to a person for the furnishing of any item or service payable in whole or in part under a federal healthcare program; or
  - ✓Purchasing, leasing, or ordering any good, facility, service, or item payable under a *federal healthcare program.*
  - There are "safe harbors."

To Induce

- 5th Circuit is expected to follow the "one purpose test," which states that the anti-kickback statute is *violated where one purpose of the payment is to induce referrals*, irrespective of the existence of other legitimate purposes.
- In *Weinbaum*, the court defined "inducement" as "remuneration with the intent to gain influence over the reason or judgment of a person making referral decisions."

Liabilities

- A felony punishable by a maximum fine of $25,000;
- Imprisonment up to 5 years; or both.
- Conviction results in an automatic exclusion from Medicare, Medicaid, and other federally funded healthcare programs.
- Civil monetary penalties of up to $50,000 and damages of up to 3 times the amount of the illegal kickback.

Texas Anti-Kickback

- Chapter 102, Occupations Code: Prohibits remuneration in cash or in kind to or from another for *securing or soliciting a patient*. (Note: The Texas anti-kickback statute is *not limited to government payors.)*
- New anti-kickback provisions added in Hum. Res. Code (Chapter 36) broaden liability beyond referral of patients to include purchase, lease, or order of any good, facility, service or item *paid for by a medical assistance program.*
- Not restricted to governmental payors.

Safe Harbors Under Anti-Kickback.

- Safe Harbors
  - investments in large publicly held health care companies;
  - investments in small health care joint ventures;
  - *space rental*;
  - equipment rental;
  - personal services and management contracts;
  - employee compensation;
  - ASCs (Ambulatory Surgery Center)
  - Physician Recruitment
- Failure to meet a safe harbor does not mean it is automatically illegal.
- If meet a federal one, state law is satisfied.

Stark Law

- Stark I pertained solely to clinical laboratory services (1989).
- Stark II added other services, including inpatient and outpatient hospital services. (DHS)
- Stark III September 2007

Stark General Rule.

- Unless an exception applies, if
  - a *physician* (or an immediate family member of the physician)
  - has a *financial relationship* with an entity,
  - then the physician cannot make a *referral* to the entity for the furnishing of *designated health services* for which Medicare or Medicaid will pay.

Unlike Anti-Kickback laws

- Stark is a *strict liability* statute.
- If a practitioner or entity implicates the statute but does not meet one of the exceptions, a violation of Stark has occurred.
- There is *no intent* requirement.

Stark Exceptions

- Rental of office space or equipment
- Bona fide employment relationships
- Personal service arrangements
- Remuneration unrelated to the provision of designated health services
- Physician recruitment and retention
- Isolated transactions
- Payments by a physician for items or services
- Investment in a Whole Hospital
- Rural Area
- Electronic Health Record

Liabilities

- Civil sanctions including nonpayment for the relevant services,
- Civil monetary penalties; and
- Exclusion from the Medicare and Medicaid programs.
- There is also a penalty of not more than $100,000 for circumvention schemes.

False Claims Acts

- Prohibits making false statements to government entities, including submitting a false or fraudulent *claim for payment*.
- Civil Penalties: Three times the amount of damages suffered by the government, plus fines of between $5,000 and $10,000 per false claim.
- Criminal penalties: Prison, fine, and exclusion from participation in Medicare and Medicaid programs.
- Pay government's cost in bringing the action or the attorney's fees in *qui tam* actions. (Allows a private person, known as a relator, to prosecute a lawsuit for the government and receive a reward.)

Proof of Violation

Government must prove:

- Actual knowledge of the false information;
- Act in deliberate ignorance of the truth or falsity of the information; or
- Act in reckless disregard of truth or falsity of information.

Qui Tam Lawsuits

- Permits whistleblowers to bring suits on behalf of the government and to share in the damages recovered.
- Whistleblower's share is usually 15 to 30% of the damages recovered.
- HHS has launched a campaign to encourage individuals covered by Medicare to analyze their physicians' bills and to report suspected instances of Medicare fraud to the government. (If fraud is proven, one-third of the amount is returned to the patient.)

Whistleblower Training

- February 8, 2006, President Bush signed the Deficit Reduction Act of 2005.
- It requires all entities receiving $5M in Medicaid payments to establish written policies and procedures for all employees, contractors and agents about fraud detection and prevention, the FCA, and whistleblower protections.
- Compliance is a condition of payment.

OIG Supplemental Compliance Program Guidance for Hospitals

- Released January 31, 2005.
- Emphasizes the need for appropriate training on fraud and abuse laws.
- Fraud and abuse laws unique to business decisions in the healthcare arena include:
  - ✓The Anti-Kickback Statutes (state and federal);
  - ✓The Stark Law; and
  - ✓The False Claims Act ("FCA").

Levels of Proof

- Preponderance of the evidence- civil cases (there is a greater than 50% chance that the claim is true)
- Clear and convincing (the contention must prove that the contention is substantially more likely than not that it is true; cases involving fraud, wills, withdrawing life support)
- Beyond a reasonable doubt- criminal cases (no other reasonable explanation that can come from the evidence presented at trial)

Laws that Facilitate Commerce

- Insurance Regulation
- Prompt Payment Laws
- Contract Laws

Insurance Regulations

- To issue insurance in Texas, a company must
  - Make an application
  - Disclose ownership, officers, etc. (with sufficient information for background checks)
  - Meet minimum net worth requirements
- Additional requirements
  - HMOs have certain covered benefit requirements
  - Appeal rights for denial of coverage decisions

Prompt Pay Laws

- Requires certain insurance carriers and health maintenance organizations to pay clean claims in a timely manner.
  - the 45th day after receipt of a clean claim in a *nonelectronic* format;
  - the 30th day after receipt of a clean claim in an *electronic* format; or
  - the 21st day after an electronically submitted *pharmacy* claim is affirmatively adjudicated.
- Penalties
  - Full billed charges
  - 18% interest

Antitrust

- Federal and State Antitrust Laws prohibit: a restraint of trade that is unreasonable.
- *Per Se* illegal: Agreements among competitors to fix prices, allocate markets, or boycott buyers of goods or services are *per se* illegal.
- Rule of Reason Analysis: Balances the competitive benefits against the negative effects on competition in the relevant market. Sherman Act Section 1, 15 U.S.C., Tex. Bus. & Com. Code Ann. Section 15.05(a).

Specific Federal Antitrust Laws

- Section 1 of the Sherman Act: Prohibits agreements to *unreasonably restrain* competition.
- Section 2 of the Sherman Act: Prohibits *monopolization*, attempted monopolization, conspiracy to monopolize.
- Section 7 of the Clayton Act: Prohibits *mergers and acquisitions* that decrease competition substantially.
- FTC prohibits *unfair methods of competition* in or affecting commerce (must be a for-profit company).

Texas Antitrust Law

- Section 15.01 of the Texas Business and Commerce Code.
- Purpose is to maintain and *promote economic competition* in Texas and provide the competitive benefits to Texas companies.

Contract laws

- What is a contract?
  - an agreement
  - between two or more persons (individuals, businesses, organizations or government agencies)
  - to do, or to refrain from doing, a particular thing
  - in exchange for something of value.

Elements of a valid contract

- Oral or written ? Many contracts can be oral, but they can be hard to prove.
- Offer and acceptance
- Consideration
- Capacity (minors, mental incapacity, impaired by alcohol or drugs)
- Intent
- Legality

Corporate Law

- Limited Liability
  - condition under which the loss that an owner (shareholder) of a business firm may incur is limited to the amount of capital invested by him in the business and does not extend to his personal assets. (i.e., Limited Liability Company)
  - Acceptance of this principle by business enterprises and governments was a vital factor in the development of large-scale industry, because it enabled business concerns to mobilize large amounts of capital from a wide variety of investors who were understandably unwilling to risk their entire personal fortunes in their investments

Corporate Law

- Choice of Entity
  - Profit/Non-profit
  - Hospital/ASC/IDTF (Independent Diagnostic Testing Facility)
  - Corporation/Partnership/PA/PC/LLC/PLLC
  - Joint venture
- Must follow corporate formalities
  - Board of Directors (or managers, etc.) meetings
  - Shareholder meetings
  - Minutes
  - Book and records
  - Use of name (Inc., LLC, etc.)
- Otherwise, may "pierce the corporate veil"

Laws to Protect Workers

- Title VII
- Americans With Disabilities Act (ADA)
- Fair Labor Standards Act (FLSA)
- Family Medical Leave Act (FMLA)
- Pregnancy Discrimination Act (PDA)
- Age Discrimination In Employment (ADEA)
- Fair Credit Reporting Act
- Equal Pay Act
- Uniformed Services Employment and Re-employment Rights (USERRA)
- ERISA
- Occupational Health and Safety Act (OSHA)
- COBRA
- HIPAA
- Texas Payday Law
- Texas Commission on Human Rights Act
- Texas Unemployment Compensation Act

At Will Employment

- **Texas is an "At-Will Employment" State:**
  - "…absent a specific agreement to the contrary, employment may be terminated by the employer or the employee at will, for good cause, bad cause, or no cause at all."
- **Some Restrictions to Termination of Employment, including:**
  - Discrimination
  - Retaliation for filing a claim or asserting rights
  - Refusal to do an illegal act
- **Written Contract**
  - A contract is almost the only way to prove than an employer has restricted the ability to terminate an employee at will.

Title VII – The 1964 Civil Rights Act

- Basic Source for Modern Employment Law
  - Texas Commission on Human Rights Act essentially mirrors Title VII – similar procedures for state court law suits with minor changes.
  - Applies to all employers with 15 or more employees.
- Prohibits discrimination and harassment based upon race, color, national origin, gender, or religion

Discrimination and Harassment

- Discrimination – generally unlawful to refuse to hire, to fire, or to treat differently in *compensation or work conditions* based upon a protected classification:
  - Race, color, national origin, gender, disability, age, religion, etc.
- Two Types of Harassment:
  - *Quid quo pro* (sexual harassment) -- Forced to choose between submission to sexual advances and employment benefits.
  - *Hostile Work Environment* -- the general atmosphere of the workplace, such as verbal and/or physical conduct that "unreasonably interferes with an individual's work or performance" or creates an "intimidating, hostile, or offensive working environment." Not just based on sex, but can be race, age, disability, etc.

Americans with Disabilities Act

- Protects “qualified individual with a disability” from discrimination.
- An individual with a disability is a person who:
  - Has a physical or mental impairment that substantially limits one or more major life activities;
  - Has a record of such an impairment; or
  - Is regarded as having such an impairment.

Americans with Disabilities Act

- An employer is required to make a *reasonable accommodation* to the known disability of a qualified applicant or employee if it *would not impose an "undue hardship"* on the operation of the employer's business.
  - "**Qualified individual with a disability" is a person who** meets the fundamental qualifications of the job, and can perform the job with or without reasonable accommodations.
  - **Reasonable accommodation may include, but is not** limited to:
    - Making existing facilities used by employees readily accessible to and usable by persons with disabilities.
    - Job restructuring, modifying work schedules, reassignment to a vacant position;
    - Acquiring or modifying equipment or devices, adjusting or modifying examinations, training materials, or policies, and providing qualified readers or interpreters.
  - **Undue hardship** is defined as an action requiring significant difficulty or expense when considered in light of factors such as an employer's size, financial resources, and the nature and structure of its operation.

Fair Labor Standards Act

- National Policy on minimum wages and overtime payments for “covered” employers and employees.

- What Does FLSA Provide?
  - Federal Minimum Wage: $7.25/hour
  - Overtime: 1 ½ times the regular rate of pay for all hours worked over 40 in a work week
  - If Texas law or union agreement provided greater protection or pay to the employee, those provisions apply.

Family Medical Leave Act

- U.S. policy that qualifying employees be granted family or medical leave.
- Applies to employees who:
  - Worked at employer at least 12 months, and worked at least 1,250 hours (25hours/week) during last 12 months, and lives within 75 miles of at least 50 people working for the same employer
- Act provides for up to 12 weeks of leave per 12-month period for eligible employees with valid medical or family reasons for leave.
- Employer is generally ***not responsible for pay*** to employee on leave (though may use accrued sick time, vacation, or personal leave during this time).

Family Medical Leave Act (cont'd)

- Qualified Family Leave:
  - Birth of son or daughter
  - Placement of child with employee for adoption/foster care
  - "Exigencies" relating to a family member who is on active military duty
  - to care for a "serious health condition" for:
    - son, daughter, spouse, or parent
    - the employee herself or himself, if the employee is unable to perform the functions of the job or position
    - next of kin, if the relative is in the Armed Forces
- Documentation – Employer may require documentation of the condition that is the basis of the request.

Age Discrimination in Employment Act (ADEA)

- May not discriminate against employees on the basis of age (40 and over).

- Bona Fide Occupational Qualifications
  - Law recognizes that with age some physical abilities are diminished – allows mandatory retirement ages for certain occupations such as pilots, law enforcement, firefighters, etc.

Texas Pay Day Laws

- Pay employees in full and on time
  - Terminated Employees must be paid no later than 6th day after termination
- Other laws mandate breaks, lunches, etc.

Laws to Benefit the Community

- Charities do not pay taxes
- Thus, they must benefit the community
- Tax-exempt laws
- Charity Care requirements

Tax-Exempt Issues

- Goal: Obtain and Maintain tax-exempt status.
- Benefits:
  - ✓exempt from federal taxes on income, sales, & real estate.
  - ✓borrow using tax-exempt bond
  - ✓donations qualify as tax-exempt/charitable

Qualifications

- Organization must be organized and operated exclusively for religious, charitable, literary, scientific, educational purposes.
- Organizational Test
- Operational Test

Organizational Test

- Articles of Incorporation limit the purposes to exempt purposes (must be present in the document);
- Articles of Incorporation not empower organization to engage in non-exempt purposes in more than an insubstantial amount;
- Distribution on dissolution is used for exempt purposes.

Operational Test

- Operates for charitable purposes
- Provides a public benefit
- Prohibits private inurement
- Political activity prohibition and lobbying limitation

Operating for a Non-Charitable Purpose

- Pay a tax: Unrelated Business Income Tax: Unrelated if the business is not substantially and causally related, other than the production of income, to accomplishing the exempt purposes of the organization.

Public Benefit

- If a private benefit is given, it must be incidental both qualitatively and quantitatively to the public benefit

Private Inurement

- Private Inurement prohibition: No part of the net earnings may inure to individuals with an insider relationship with the charitable organization.
- Insiders – Officers, Directors, Trustees, Key Employees (ODTKE), including Medical Staff.

Physician Recruitment

- IRS opinion in 1997: Tax-exempt organization can pay compensation to a physician under a physician recruitment agreement so long as:
  - ✓Furthers the charitable purpose
  - ✓No private inurement (usually recruited physician is not an insider)
  - ✓Community benefit/need
  - ✓Not illegal under Anti-kickback or Stark

Charity Care Requirements

- Under the Texas law, Texas nonprofit hospitals are required to meet one of three standards, by providing:
  - Charity care and government-sponsored indigent health care at a *reasonable level in relation to community needs*, available resources and the tax-exempt benefits received by the hospital (the **"Reasonableness Standard")**, or
  - Charity care and government-sponsored indigent health care equal to *100 percent of the hospital's tax-exempt benefits*, excluding federal income tax (the "**100% of Tax-exempt Benefits Standard"),** or
  - Charity care and community benefits equal to at *least 5 percent of the hospital's net patient revenues*, with charity care and government sponsored indigent health care equal to at least 4 percent of the hospital's net patient revenues, and at least 1 percent in other community benefits (the "**Charity Care and Community Benefits Mix").**

How Charity Care is Calculated

- "Charity care" means the unreimbursed costs to the hospital of providing, funding or otherwise financially supporting health care services to the financially or medically indigent.
  - Hospitals may establish eligibility criteria for their applicable charity care policies, but "financially indigent" criteria may not exceed 200% of the federal poverty law, for consideration as "charity care" for purposes of calculating compliance with the law.
- "Government-sponsored indigent health care" means the unreimbursed cost to a hospital of providing health care services to recipients of Medicaid and other federal, state, or local indigent health care programs, eligibility for which is based on financial need.
- Bad debt is not considered "unreimbursed care" for the purposes of determining the amount of Community Benefit, but it is considered an expense when calculating the cost to charge ratio of the hospital under GAAP.

Other defined terms

- "Community Benefit" generally means unreimbursed cost to a hospital of providing charity care, government-sponsored indigent health care, donations, education, research and subsidized health services. It does not include any taxes or government assessments paid by the hospital.
- "Net Patient Revenue" is an accounting term calculated in accordance with GAAP for hospitals. Essentially Gross Revenue less contractual adjustments.

Oversight at the Federal Level

- Internal Revenue Service
- U.S. Department of Health and Human Services at www.hhs.gov.
- CMS: Centers for Medicare and Medicaid Services at www.cms.hhs.gov
- OIG: Office of Inspector General at www.oig.hhs.gov
- Department of Justice at www.usdoj.gov

Oversight at the State Level

- Texas Department of State Health Services at www.dshs.state.tx.us
- State Attorney General at www.oag.state.tx.us
- State Medicaid – Office of Inspector General at www.tdg.state.tx.us.general/inspector.gnl-home.htm
- Texas Medical Board/Nursing Board, etc.

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