Laws and Regulations

Presentation to the ACHE Board of Governors Exam Study Group

Denise Montgomery
October 30, 2003
Chuck Davis
January 6, 2011
3rd Edition presented by…….
Christine Winn, FACHE
May 29, 2013
4th Edition presented by….
Christine Winn, FACHE

Disclaimer

- **The following information has been extracted from a wide variety of sources, for the sole purpose of preparing interested healthcare professionals for the Board of Examiners exam of the American College of Healthcare Executives.**
- **You should always rely on competent legal counsel for advice in matters that have a legal consequence.**

Setting the Stage

- **Sixteen (16) Laws and Regulations questions on BOG**
- **8% of your Exam**

Areas to Cover….

- **Basic Knowledge of the following**
  - Human Resources Law
  - Confidentiality principles and laws
  - Corporate Compliance – particularly physician contracting and antitrust, tax status
  - Medicare/Medicaid/third party payment regulations
  - Inspection criterion – JC, OSHA, NRC
  - Patient Rights laws and regulations

Human Resource Law

- **FMLA – Family Medical Leave Act of 1993**
  - Covered employers must grant an eligible employees total of 12 work weeks of unpaid leave during any 12-month period for one or more of the following reasons:
    - for the birth and care of the newborn child of the employee;
    - for placement with the employee of a son or daughter for adoption or foster care;
    - to care for an immediate family member (spouse, child, or parent) with a serious health condition; or
    - to take medical leave when the employee is unable to work because of a serious health condition.
- **FLSA – Fair Labor Standards Act**
  - Federal labor law of general and nationwide application, including Overtime, Minimum Wages, Child Labor Protections, and the Equal Pay Act.
  - FLSA requires overtime compensation (at time and one-half) for all "hours worked" over a prescribed "threshold" (typically 40 hours per week), for "nonexempt" employees.
    - With a few exceptions, to be exempt an employee must (a) be paid on a salary basis, and also (b) perform exempt job duties.
    - An employee who is not paid on a salary basis is nonexempt no matter what kind of work s/he does.

Human Resource Law, cont.

- **EEOC – Equal Employment Opportunity Commission created Equal Employment Opportunity Laws**
  - Title VII of the Civil Rights Act of 1964 (Title VII), which prohibits employment discrimination based on race, color, religion, sex, or national origin;
  - Equal Pay Act of 1963 (EPA), which protects men and women who perform substantially equal work in the same establishment from sex-based wage discrimination;
  - Age Discrimination in Employment Act of 1967 (ADEA), which protects individuals who are 40 years of age or older;
  - Title I and Title V of the Americans with Disabilities Act of 1990 (ADA), which prohibit employment discrimination against qualified individuals with disabilities in the private sector, and in state and local governments;
  - Sections 501 and 505 of the Rehabilitation Act of 1973, which prohibit discrimination against qualified individuals with disabilities who work in the federal government
  - Civil Rights Act of 1991, which, among other things, provides monetary damages cases of intentional employment discrimination

Human Resource Law, cont.

- **ERISA – Employee Retirement and Income Security Act of 1974**
  - Regulations specify the employer's obligation
    - To offer pensions
    - To contribute to them if offered
    - To vest those contributions
    - To fund pension liabilities through trust arrangements
- **Workers Compensation Laws**
  - Designed to ensure that employees who are injured or disabled on the job are provided with fixed monetary awards, eliminating the need for litigation
  - Also provide benefits for dependents of those workers who are killed because of work-related accidents or illnesses
- **Americans with Disabilities Act of 1990**
  - Designed to ensure equal access to public opportunities, buildings and way finding
  - Updated under the American Recovery and Reinvestment Act of 2009
  - Assures standards in providing "reasonable accommodation"
  - Applies to employees AND patients (All Americans)
  - Added improved 2010 ADA Standards for Accessible Design
    - Access to Medical Care For Individuals with Mobility Disabilities

Privacy Overview

- **Fear → Electronic transmission of health information may lead to widespread dissemination of private and sensitive information**
- **Solution → Privacy Regulations**

HIPAA

- In 1996, Congress passed the Health Insurance Portability and Accountability Act ("B"), which addresses a range of confidentiality related issues, including privacy and security, that impact the sharing of information in and among healthcare organizations and providers.
- HIPAA impacts day to day hospital and healthcare facility operations, including patient registration, medical transcription, medical records, pharmacy operations, pre-certification and pre-authorizations for treatment, eligibility and referrals, claims processing, and patient billing.

HIPAA

- **Three main categories of provisions:**
  - Transaction Code Sets – standards designed to streamline the process of healthcare claims, reduce paperwork and maximize the utilization of the electronic data interchange (EDI).
  - Privacy Rule – enables patient to have greater access to their medical record and more control over how their PHI is used and disclosed outside a covered entity.
  - Security Rule – address four distinct areas:
    - Administrative procedures
    - Physical safeguards
    - Technical security services
    - Technical security mechanisms

Privacy Overview

- **Treatment:**
  - Provision of care
  - Coordination of care with other providers
  - Consultation with other providers
  - Referral to another provider

Privacy Overview

- **Use and Disclosure**
  - Must make a "good faith" effort to obtain patient's acknowledgement of Notice of Privacy Practices
  - Acknowledgement must be in writing
  - Only need to obtain acknowledgement once
- Assuming good faith efforts, may use or disclose information for Treatment, Payment, or Health Care Operations ("TPO") without acknowledgement or authorization

Privacy Overview

- **Required Disclosure → Authorization Not Needed**
  - Public health activities
  - Reporting child abuse
  - Reporting other abuse, neglect, domestic violence, etc.
  - Health oversight activities
  - Judicial and administrative proceedings
  - Law enforcement purposes
  - Otherwise required by law

Privacy Overview

- **Permitted Use → Authorization not needed**
  - Decedents:
    - Funeral directors, coroners, and medical examiners
    - Cadaveric organ, eye, tissue donation
  - Research
    - Authorization waived by IRB or a Privacy Board
    - De-identified or limited data set
  - Serious threat to health or safety
  - Government functions
    - Armed Forces, national security, correctional institutions
  - Workers' compensation

HIPAA

- **Potential Penalties for Non-Compliance**
  - Could result in the imposition of civil monetary penalties of $100 per violation up to $25,000 per person per year for each requirement or prohibition violated.
  - Criminal penalties may be up to $250,000 plus prison time.

Corporate Compliance: Rationale and Benefits

Compliance programs are essential "to prevent violations of law whether criminal of non-criminal, … for which the organization is, or would be, liable." (Organizational Sentencing Guidelines [and related amendments], effective November 1, 2004).

Compliance addresses organizational, general public and governmental goals to reduce fraud and abuse, enhance provider operations, improve quality and corporate integrity, and reduce cost.

Compliance Program Components

- **Identify a compliance officer/committee; someone in charge.**
- **Develop policies and procedures, code of conduct, and standards; put in writing.**
- **Open lines of communications (hotline); listen without retaliation.**
- **Train and educate, tell employees what you expect.**
- **Monitor and audit, make sure program is working.**
- **Respond to detected deficiencies and fix them.**
- **Enforce disciplinary actions.**
- **Self report. Promptly report when you have credible evidence, e.g. OIG recommends payback of overpayments within 60 days of discovery.**

Corporate Compliance: Risk Areas

Hospital Corporate Compliance Risk Areas

- **Substandard care – role of quality assurance**
- **HIPAA Privacy**
- **Billing Medicare or Medicaid substantially in excess of usual charges**

Compliance -Hill-Burton Act

- **Provided federal financing for the construction and expansion of private health care facilities through the early 1960's**
- **Facilities were required to provide a reasonable volume of free care and to make the facility available to persons in the community**
- **Free care interpreted to extend for 20 years after the financing – most hospitals no longer held to this**
- **Community service obligation remains indefinitely**

Compliance -Tax Exemption Issues

- **Section 501(c) (3) Exemption Standards**
  - Must be organized and operated exclusively for charitable purposes
  - Cannot have even one substantial noncharitable purpose, regardless of the number or importance of the charitable purposes
  - May not benefit private interests
  - Does not prohibit payment of reasonable compensation for management services
  - Hospital exemption also requires
    - Community board
    - Open staff with medical staff privileges available to all qualified physicians in the area
    - 24-hour emergency room
    - Provision of charity care to the extent of its financial ability
- **Compliance Challenges – 990 Filing Key to demonstrated activities**

Compliance -Tax Exemption Issues, cont.

- **Revenue Ruling 98-15**
  - IRS reviews whole hospital joint ventures in analyzing these joint ventures they established a two-prong test
  - Two-prong test is used to determine whether the joint venture will void a not-for-profit hospital's tax exempt status
    - First prong is the "purpose test"
      - Test analyzes the primary purpose of the joint venture
      - If the primary purpose is to pay dividends to the owners of the joint venture, then the test failed
      - If the primary purpose is to accomplish a charitable purpose, then the first prong is satisfied
    - Second prong is the "control test"
      - Rule requires that the tax-exempt entity in the joint venture retain enough control and have all the powers that are necessary to guarantee that the operations of the joint venture are exclusively for public purposes

Corporate Integrity

- **Sarbanes Oxley: Highlights**
  - Independent and competent audit committees
  - Auditors: periodic rotation of lead audit partner
  - Auditors: prohibited for providing non audit work
  - CEO and CFO must certify the accuracy of financial statements.
  - Insider transactions and conflicts of interest
  - Disclosure
  - Whistleblowers protections
  - Document destruction prohibitions with criminal sanctions (impact all organizations)

Compliance -Stark Laws

- **Stark Regulations**
  - Prohibit physicians from referring Medicare and Medicaid patients to an entity where the physician or an immediate family member has a financial relationship with the entity for clinical laboratory services; physical therapy services; occupational therapy services; radiology, including MRI, CAT and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices; home health services and supplies; outpatient prescription drugs; and inpatient and outpatient hospital services.
  - Almost every year CMS has modified its interpretive guidelines to adjust to findings in the field and in the Courts

Stark Law

- **Stark Law – Federal Physician Self Referral Proscription (Social Security Act § 1877; 42 U.S.C. § 1395nn)**
  - Prohibition: Stark Law prohibits **physicians** from ordering "**designated health services**" for Medicare patients from entities with which the physician (or an immediately family member) has a **financial relationship**
  - Two versions
    - Stark I (September 13, 1995) applied only to clinical laboratory services
    - Stark II (proposed in January 1998
      - Phase I issued on January 4, 2001) expands coverage to other designated health services
      - Phase II issued on March 25, 2004
  - Penalties: Civil sanctions, including denial of payment, refunds of amounts collected, a civil monetary penalty of up to $15,000 and up to $100,000 for referral schemes

Physician Self Referral Law (Stark)

- A physician may not refer a Medicare or Medicaid patient for designated health services (DHS) to an entity with which the physician or his/her immediate family members have a financial relationship, unless an exception applies.
- The law is intended to protect against unnecessary care and overuse of services driven not by medical need but by a financial gain.
- No intent is required.

Physician Self Referral Law (Stark)

- **Stark Exceptions: Key Concepts**
  - Business arrangements between entities/individuals must fit within an exception.
  - The following are common elements of many of the exceptions:
    - Arrangements need "arms length negotiation"
    - Must be commercially reasonable
    - Must be signed written agreements set in advance
    - Set at fair market value

Physician Self Referral Law (Stark)

- **Penalties**
  - Denial of payment of recoupment
  - Civil monetary penalties up to $15,000 per service/billing; $100,000 for each scheme.
  - Exclusion from Medicare and Medicaid programs.

Fraud and Abuse

- Enforcement activities have increased over recent years.
- Activities that constitute violations may be subtle and not fit the typical profile of criminal behavior or abusive practices.
- Providers believe these practices are often within Medicare guidelines.

False Claims Act

- **At Issue:**
  - Preparation and submission of incorrect bills.
  - Failure to disclose when overpayments were made.
  - Inaccurate coding, upcoding, unbundling of services for global rates, billing for unnecessary services.
  - Duplicate billing, insufficient documentation, false or fraudulent cost reports.

False Claims Act

Elements of a False Claim

- Knowingly presenting the US government
- False or fraudulent claim for payment or approval
- No intent to defraud is required
- Knowledge
  - Actual knowledge
  - Reckless disregard for what is true and accurate

Compliance -False Claims Act

- **1986 - a modern version of the False Claims Act was passed**
- **Law was designed to curb fraud against the Federal Treasury (the Government)**
- **Government does not require a whistle blower to file suite but the potency of the law is due to its qui tam provision**
  - Qui tam provision encourages whistle blowers to expose fraud in return for a substantial percentage of money the government recovers
  - If the Dept of Justice intervenes, the whistle blower will receive an award between 15 % and 25% of the government's recovery
  - If the Dept of Justice does not intervene and the whistle blower proceeds on his or her own, they are entitled to between 25% and 30% of the recovery
- **FCA has been used again healthcare providers in the following areas: billing for services or supplies not actually provided, billing for nonreimbursable services, and using false diagnosis to justify claims**
- **Based on a 2001 Federal Court of Appeals ruling, a claim can be false either because the service delivered was grossly inadequate or because the provider did not comply with a quality-of-care standard that was a prerequisite for payment**
- **Government is able to collect up to 3 times the amount of a false claim, or as much as triple the amount of the claims for services tainted by kickbacks, plus up to $10,000 per false claim**
- **1987 - the inspector general's office was given authority to punish providers by excluding them from Medicare and Medicaid**
- **1997 - the inspector general's office was given authority to assess a civil penalty of $50,000 per alleged kickback plus up to 3 times the amount of the alleged remuneration**

Anti-Kickback Statue

- **Anti-Kickback Statute (Social Security Act § 1128B(b); 42 U.S.C. § 1320a-7b(b))**
  - Prohibited Activity - Proscribes the payment or receipt of money or other remuneration in return for, among other things, "purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering" any item or service paid for by a federal government health care program. Includes kickbacks, bribes and rebates
  - Penalties - $25,000 and imprisonment of up to 5 years per each offense. Violators also subject to exclusion from Medicare. Government may also collect treble damages plus $50,000 for each violation

Anti-Kickback Statue

Practitioner Recruitment Safe Harbor

– In 1999, the OIG added a safe harbor for physician recruitment activities paid to a physician to induce a physician who has been practicing his or her specialty for less than 1 year to relocate to qualified medically underserved areas. Criteria include the following:

- Written agreement specifying the parties' obligations
- At least 75% of the revenues must be generated from new patients
- Term of no more than 3 years
- No referral requirement
- No restrictions on where physician can maintain medical staff privileges
- Remuneration may not vary with volume or value of referrals
- Physician must agree to treat patients receiving Medicare benefits in a nondiscriminatory manner
- At least 75% of the revenues of the new practice must be generated from patients residing in medically underserved area

Anti-Kickback Statue

- **Anti-Kickback Guidance**
  - Special Fraud Alerts – addresses conduct the OIG believes is impermissible
  - OIG Advisory Opinions – As a result of HIPAA, a mechanism was created for obtaining advisory opinions on whether conduct violates certain fraud and abuse regulations. Opinions are binding only on the parties, but are instructive to OIG's perceptions
  - Special Bulletins – OIG Special Bulletin on Contractual Joint Ventures. Addresses areas that the OIG believes are suspect to fraud and abuse

Compliance -Antitrust Laws

- **Sherman Act**
  - Passed in 1890
  - Section 1 - Prohibits contracts, combinations and conspiracies that unreasonably restrain trade
  - Section 2 – Prohibits monopolization, attempts to monopolize and conspiracies to monopolize
  - Supreme Court interpreted Sherman Act to prohibit only “unreasonable” restraints of trade
  - Per Se and Rule of Reason Analysis are used to determine if a restraint of trade is in violation of the Sherman Act - A restraint may be “unreasonable either because it fits within a class of restraints that has been held to be ‘per se’ unreasonable or because it violates the ‘Rule of Reason’
    - A Per Se violation is conduct that falls within a category deemed to be Per Se unlawful, that is conduct so bad, the conduct itself constitutes a Sherman Act violation
      - Typically involves an agreement or conspiracy among actual or potential competitors
    - The Rule of Reason analysis requires inquiry into the reasonableness of the business practices and requires courts to actually balance the merits of the proposed conduct versus any potential anti-competitive effects it may have. If the anti-competitive effect outweighs the benefits, the conduct is deemed to violate the Sherman Act.

Anti-Trust Laws

- **Concerns in health care transactions:**
  - Control
  - Consolidation
  - Anti-competition

Anti-Trust Laws

- **Mergers & Acquisitions**
  - Clayton Act, Section 7 – prohibits anti-competitive acts
    - (i.e. mergers and acquisitions that lessen competition)
  - Sherman Act, Section 1 – prohibits unreasonable restraint of trade
    - (i.e., monopolies)
  - FTC Act, Section 5 – prohibits unfair trade and business
  - Hart-Scott Rodino Act – requires a premerger notification report to the FTC and DOJ & observance of a statutorily mandated waiting period

Anti-Trust Laws

- **FTC and DOJ utilize *The Horizontal Merger Guidelines***
- **Lessons learned:**
  - A merger of the only hospitals in a community is likely to be permitted if other hospitals are located close enough to be considered competitors
  - The opinion of third-party payors will be critical to the outcome
  - Neither the DOJ & FTC or the courts have accepted arguments by merging acute care hospitals that ASCs be included in their relative product market (although frequently characterized as competitors)

Anti-Trust Laws

- **Transaction Best Practices**
  - Avoid certain activities pre-closing:
    - Allocating services, customers or territories
    - Agreeing not to deal with certain customers or suppliers
    - Early implementation of post-merger consolidation or integration
  - Exchange information with caution, or redact
    - Price or price-related information (including fee schedules, capitation rates and credit terms)
    - Customer or payor information, including customer lists and information relating to terms dealing with customers or payors

Compliance -EMTALA

- **EMTALA – Emergency Medical Treatment and Active Labor Act**
  - "Anti-Dumping Law" - Prohibits hospitals from improperly transferring or dumping emergency patients from one hospital to another based on their ability to pay
  - Required to provide an appropriate medical screening exam
  - If patient has an emergency medical condition, hospital is required to provide treatment to stabilize the condition or a proper transfer in accordance with the requirements of the statute
    - Transfer if patient requests it or if it physician certifies that the benefits of the transfer outweigh the risks
  - Hospital may not delay screening exam and treatment to inquire about patient's payment methods or insurance status (includes managed care patients)
  - Provision of emergency care without regard for ability to pay is a requirement for participation in the Medicare program

EMTALA

- **Violations**
  - EMTALA violations are reported via complaints to the government by other hospitals, patients, families, physicians or hospital employees.
  - Violations may be reported to the hospital or directly to the regulatory agency like DOH or CMS.
  - Investigations by state agencies, on behalf of CMS, may occur without warning.
  - Hospitals – civil monetary penalties of up to $50,000 for negligent violations; civil liability for costs of the receiving hospital plus equitable relief, civil liabilities for damages under state law plus equitable relief and potential exclusion from Medicare.

Office of the Inspector General (OIG)

- **Office within the Department of Health and Human Services**
- **Responsible to protect health and welfare of Dept of Health & Human Services program beneficiaries (i.e. Medicare and Medicaid participants)**
- **Focus on compliance/very influential**
- **Audits (investigatory powers)**
- **Works in concert with the Department of Justice**
- **Contracts Recovery Audit Contractors (RACs), which identify potential fraud for investigation**

The Medicare Program

MEDICARE: ***A social health insurance program that provides universal hospital coverage for Americans who are 65 years of age or older***

- **Enacted in 1965**
- **Established under Title XVIII of the Social Security Act**
- **Has 4 parts (A, B, C, D)**

The Medicare Program

- **Medicare Part A**
  - Covers inpatient hospital care, skilled nursing facility care, hospice, and home health care
  - Financed through the federal Hospital Insurance Trust Fund, which was established at the inception of the program
  - Funded by payroll taxes from workers and employers

The Medicare Program

Medicare Part B

- Covers physician, outpatient hospital, home health, and outpatient ambulatory services; speech and physical therapy; rehabilitation; and other diagnostic care
- Is a voluntary program – Part A beneficiaries may elect to have Part B coverage for a monthly premium deducted from their Social Security checks
- Balance financed through the Supplementary Insurance Trust Fund
- Funded by individual premiums, general tax revenues, and other sources

The Medicare Program

- **Medicare Part C**
  - A relatively new, voluntary program for Medicare beneficiaries who elect private health care coverage for a monthly premium
  - Created by the Balanced Budget Act of 1997
  - Commonly referred to as “Medicare+Choice”

The Medicare Program

- **Medicare Part D**
  - Prescription drug benefits
  - Implemented in 2006
  - Available only through private healthcare plans (either Medicare Advantage or a free-standing prescription drug plan)

The Medicare Program

- **Secondary Payor Rule**
  - Medicare does not pay for services for which Medicare is not the PRIMARY payor

- **“Medigap”**
  - Medicare beneficiaries have the option of purchasing supplemental health insurance coverage from private commercial insurers

The Medicaid Program

MEDICAID: ***A means-tested assistance program that provides medical, nursing home, and catastrophic insurance coverage to disabled, low-income, and medically-indigent populations***

- **Enacted in 1965**
- **Established under Title XIX of the Social Security Act**

The Medicaid Program

- **Medicaid is a federal/state cost-sharing program**
  - State participation is voluntary
  - Administered at the discretion of the State
  - Financed through general revenue – there is no Medicaid trust fund
  - The federal government helps states pay for the Medicaid program via a matching formula that is adjusted annually

The Medicaid Program

Medicaid is a federal/state cost-sharing program

- State participation is voluntary
- Administered at the discretion of the State
- Financed through general revenue – there is no Medicaid trust fund
- The federal government helps states pay for the Medicaid program via a matching formula that is adjusted annually

HQIA – Physician Credentialing/Peer Protection

- **Healthcare Quality Improvement Act of 1986**
  - Federal Law that provides immunity for participation in certain peer review activities
  - Challenges to immunity are increasing, proximate cause holding hospital responsible for privileging neglectful physicians
  - In order to qualify for immunity, the review process must meet a four-part test.
    - Must be taken under the reasonable belief that the action was in furtherance of quality healthcare and
    - After a reasonable effort to obtain the facts of the matter and
    - After notice and hearing procedures are afforded to the physician involved or after such other procedures are fair to the physician under the circumstances and
    - Under reasonable belief that the action was warranted by the facts
- **Credentialing**
  - Covered by HCQIA
  - Courts accept Medical Staff privileges when supported by "reasonable" evidence
  - All entities performing credentialing should document and verify a provider's current credentials which should include
    - License to practice with the state
    - Controlled substances registration for providers who prescribe such drugs
    - Professional liability insurance
    - References
    - Background Checks, including National Practicianer's Data Bank
    - Eligible for, working toward or attained Board certification
    - Photo Identification
  -

Federal Regulation Process

- **Member of Congress proposes a bill**
- **Both houses of Congress need to approve the bill, if it is approved it goes to the President who has the option to either approve it or veto it**
  - If approved, the new law is called an act and the text of the act is known as a public statute
- **Once the act is passed, the House of Representatives standardizes the text of the law and publishes it in the US Code**
  - The US Code is the official record of all federal laws
- **Congress then authorizes certain federal agencies to create regulations**
  - In healthcare, the Department of Health and Human Services is responsible
  - Regulations set specific rules about what is legal and what is not
  - The specified agency proposes the regulations in the Federal Register as a "Notice of Proposed Rulemaking"
  - This allows the public the opportunity to comment on the the regulations
  - The agency considers the comments, revises the regulation accordingly and issues a final rule
- **Once the regulation is completed and has been printed in the Federal Register as a final rule, it is "codified" by being published in the Code of Federal Regulations**
- **CFR guides CMS standards/regulations – upon which state regulations are based**
- **CMS can perform state survey validation surveys of their own….**

Certificate of Need (CON)

- **A requirement in many States to justify major expenditures in an attempt to contain cost of the aggregate healthcare delivery due to redundance and waste**
- **Frequently driven by the politics of the market, not the need to the community**
- **Healthcare industry does not respond to normal competitive forces. CON has not shown to contain costs as the CON Theory prescribed.**
- **CON does allow the State to impose other conditions that would otherwise be filled, i.e. indigent care, emergency care, maternity care, etc.**

Joint Commission

- **JC – Joint Commission**
  - Accredits hospitals, integrated delivery networks, ambulatory facilities, nursing homes, home care organizations, behavioral health organizations and clinical laboratories
  - Accreditation is voluntary but is required by Medicare and most health insurers so, 95% of all institutions are accredited
  - Criteria are more clinically oriented that state licensure programs. They address structural (presence of adequate resources including trained staff) and process (use of a recommended process or procedure) indicators
  - Key patient safety goals and sentinel event alerts

Informed Consent

- **Criteria**
  - An investigator shall seek consent only under circumstances that provide the individual sufficient opportunity to consider whether or not to participate
  - Any information given shall be in a language that is understandable
  - Cannot require the subject to waive any rights or grant a release from liability or negligence
- **Approval of Informed Consent**
  - Must be documented by use of a written consent form approved by the Institutional Review Board and signed by the individual
  - A copy must be provided to the individual
  - The form must either embody all the necessary elements of “informed consent”, or the individual must sign an acknowledgement that the necessary elements were communicated orally

Patient Rights

- Notice Form
  - Describes permitted uses and disclosures of PHI, individual rights, and privacy policies
  - Post prominently at premises and on website
  - Deliver at “first service”
  - Make available for patients to take home
- Access/copy records for own information
- Right to request restrictions in use
- Procedure to request amendment/correction
- Complain
- Accounting of disclosures
- Informed Consent

Patient Bill of Rights (28 Pa. Code 03.22)

- **The hospital governing body shall establish a Patient's Bill of Rights not less in substance and coverage than the minimal Patient's Bill of Rights provided by subsection (b).**
- **The following are minimal provisions for the Patient's Bill of Rights:**
  - A patient has the right to respectful care given by competent personnel.
  - A patient has the right, upon request, to be given the name of his attending physician, the names of all other physicians directly participating in his care, and the names and functions of other health care persons having direct contact with the patient.
  - A patient has the right to every consideration of his privacy concerning his own medical care program. Case discussion, consultation, examination, and treatment are considered confidential and should be conducted discreetly.
  - A patient has the right to have all records pertaining to his medical care treated as confidential except as otherwise provided by law or third-party contractual arrangements.
  - A patient has the right to know what hospital rules and regulations apply to his conduct as a patient.
  - The patient has the right to expect emergency procedures to be implemented without unnecessary delay.
  - The patient has the right to good quality care and high professional standards that are continually maintained and reviewed.
  - The patient has the right to full information in layman's terms, concerning his diagnosis, treatment, and prognosis, including information about alternative treatments and possible complications. When it is not medically advisable to give such information to the patient, the information shall be given on his behalf to the patient's next of kin or other appropriate person.
  - Except for emergencies, the physician must obtain the necessary informed consent prior to the start of any procedure or treatment, or both. Informed consent is defined in section 103 of the Health Care Services Malpractice Act (40 P. S. § 1301.103).
  - A patient or, in the event the patient is unable to give informed consent, a legally responsible party, has the right to be advised when a physician is considering the patient as a part of a medical care research program or donor program, and the patient, or legally responsible party, must give informed consent prior to actual participation in such a program. A patient, or legally responsible party, may, at any time, refuse to continue in any such program to which he has previously given informed consent.

Patient Bill of Rights (28 Pa. Code 03.22), cont.

- A patient has the right to refuse any drugs, treatment, or procedure offered by the hospital, to the extent permitted by law, and a physician shall inform the patient of the medical consequences of the patient's refusal of any drugs, treatment, or procedure.
- A patient has the right to assistance in obtaining consultation with another physician at the patient's request and own expense.
- A patient has the right to medical and nursing services without discrimination based upon race, color, religion, sex, sexual preference, National origin or source of payment.
- The patient who does not speak English should have access, where possible, to an interpreter.
- The hospital shall provide the patient, or patient designee, upon request, access to all information contained in his medical records, unless access is specifically restricted by the attending physician for medical reasons.
- The patient has the right to expect good management techniques to be implemented within the hospital considering effective use of the time of the patient and to avoid the personal discomfort of the patient.
- When medically permissible, a patient may be transferred to another facility only after he or his next of kin or other legally responsible representative has received complete information and an explanation concerning the needs for and alternatives to such a transfer. The institution to which the patient is to be transferred must first have accepted the patient for transfer.
- The patient has the right to examine and receive a detailed explanation of his bill.
- The patient has a right to full information and counseling on the availability of known financial resources for his health care.
- A patient has the right to expect that the health care facility will provide a mechanism whereby he is informed upon discharge of his continuing health care requirements following discharge and the means for meeting them.
- A patient cannot be denied the right of access to an individual or agency who is authorized to act on his behalf to assert or protect the rights set out in this section.
- A patient has the right to be informed of his rights at the earliest possible moment in the course of his hospitalization

Sample Question Series……

Which of the following best describes the responsibility of a hospital with an emergency department (ED) when a person comes to the ED for Examination or treatment?

a. The hospital must admit the patient for observation and treatment if an emergency condition exists.

b. The hospital must provide an appropriate medical screening to determine whether an emergency condition exists and, if so, stabilize the condition.

c. The hospital may inquire as to the individual's method of payment or insurance status prior to rendering services.

d. If the individual is uninsured, the hospital must transfer the patient to the nearest public hospital designated for the care and treatment of medically indigent persons.

Which of the following is not an advantage of an effective Corporate Compliance Program for a healthcare organization?

a. Initiating immediate and appropriate corrective actions.

b. Costs of implementation and operations.

c. Developing processes to allow employees to report potential problems

d. Identifying and preventing criminal and unethical conduct.

Participating providers in the federal Medicare program must:

a. Be accredited by the Joint Commission.

b. Serve Medicaid beneficiaries.

c. Meet the Conditions of Participation.

d. Be in compliance with state Certificate of Need laws.

Which physician organization is responsible for accrediting residency training programs?

a. ACGME

b. AAMC

c. CAT

d. BPQA

Which of the following are important aspects to consider when establishing a joint venture?

a. Joint ventures involve independent management teams and independent governance structures.

b. Joint ventures involve capital investment by all parties, can be difficult to dissolve, and are usually expected to be permanent.

c. Joint ventures are managed like an internal organization and are usually renegotiated annually.

d. Joint ventures are developed to acquire portions of the parent organizations and are generally accepted as irreversible.

The overall goal of the HIPPA Act of 1996 is:

a. To ensure the privacy and confidentiality of patient medical records.

b. To standardize the sharing of clinical and administrative information.

c. To strengthen healthcare data security standards and practices.

d. Improve portability and continuity of health insurance, combat fraud.

Congress enacted Stark II to prohibit which of the following?

a. A physician or an immediate family member from referring a patient to an entity with which they have a financial relationship.

b. Hospitals and physicians from partnering to build in-patient acute care facilities.

c. Hospitals and physicians from joint venturing in the offering of outpatient imaging centers.

d. A hospital from referring a patient to a wholly-owned entity of which it has total ownership.

Under the Emergency Medical Treatment and Active Labor Act (EMTALA):

a. Benefits only those who are uninsured and unable to pay.

b. Originated due to concerns of patient dumping.

c. Excludes women in active labor.

d. Does not require facility to forward medical records to the second facility.

Which of the following courts is often given jurisdiction to hear cases involving such matters as surgery for an incompetent person or the involuntary commitment of a mentally ill person?

a. Family court.

b. Juvenile court.

c. Appellate court.

d. Probate court.

Which of the following regulations exempted self-funded employer sponsored health insurance plans from state insurance regulation?

a. BBA

b. TEFRA

c. COBRA

d. ERISA

The reimbursement method that was first adopted by Medicare and later by most third party payers is known as:

a. ICD-9.

b. RBRVS.

c. RUG.

d. DRG.

Which one of the following conditions must be met for human subjects to be used in a medical research program?

a. No suitable animal model exists for use instead of people.

b. The research program has been approved by the medical staff.

c. The research program has been approved by the governing authority.

d. Risk should be clearly explained in understandable language to each individual subject.

Thank you and Questions …..

Winn-christine@cooperhealth.edu