

American College of Healthcare Executives of Georgia

Board of Governors Exam

Legal and Regulatory Environment

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Robert G. Eaton Legal Background

- * I received my law degree (J.D.) from the University of Southern California .
- * I have been a member of five state bars during my career.
- * I served as General Counsel of the District of Columbia Hospital Association.
- * I served as General Counsel and Director of Government Relations for FHC Managed Health Services.
- * I served and Director of Government Relations and Health Policy for Howard University Hospital.
- * I served as Compliance and Privacy Officer for State University of New York Stony Brook University Hospital.
- * I have taught health law for GSU and UMUC.
- * I have practice law in my own law practice.

Disclaimer

- * The slides have been developed to assist ACHE of Georgia members in preparation for the ACHE Board of Governors examination.
- * They are based on legal concepts and do not constitute legal advice in an attorney- client relationship context.

Confidentiality Laws

- * Health Information Portability and Accountability Act (HIPAA) Privacy Regulations
- * Privacy Act of 1974
- * Freedom of Information Act
- * Release of Information

HIPAA Privacy Regulations

- * HIPAA privacy regulations pertain to protected health information (PHI) of covered entities under the Act.
- * Providers can disclose patient information without patient consent for the purposes of treatment, payment or operational purposes.
- * Providers cannot use patient information for marketing purposes without written authorization.
- * Disclosures of patient information may only be the minimally necessary amount of information for the disclosure's purpose.

HIPAA Privacy Regulations (con't)

- * If state law is more stringent i.e. protects patient privacy better than HIPAA, state law supersedes HIPAA.
- * Providers should have written policies and procedures regarding the use, management, and disclosure of patient information.
- * Providers should also have business associate agreements with business partners if patient information is disclosed to them.

HIPAA Privacy Regulations (con't)

- * Providers should have a privacy officer to investigate privacy complaints and train employees on privacy regulations.
- * Patients can report privacy violations to the U.S. Department of Office of Health and Human Services Office of Civil Rights.
- * There is no private right to sue under HIPAA.
- * PHI is required to be reported to governments include births/deaths, infectious diseases, child abuse, etc.

HIPAA Disclosure in Legal Proceedings

- * HIPAA permits disclosure with subpoenas and other court-ordered releases.
- * Court generally do not permit discovery of PHI of persons who are not parties.
- * States generally protect QI and peer review committee activities to encourage self regulation.

Permission not required to Report PHI to Legal Authorities

- * Police reports
- * Collection and testing samples
- * Confirm patient presence in a facility
- * Removal of bullets/other foreign objects

Other Privacy Laws/Requirements

- * Privacy Act of 1974 created safeguards to privacy information pertaining misuse of federal records, allowed access by the individual to records pertaining to them held by federal agencies, and created a privacy protection safety commission.
- * Freedom of Information Act requires the full or partial disclosure of unreleased information controlled by the United States Government upon request.
- * Patients have a right to a copy of their medical records.
- * Providers should have policies and procedures regarding when patient information can be released.
- * State law governs how long medical records must be kept.

Ethics

- * Ethics is a branch of philosophy that seeks to understand the nature, purposes, justification, and founding principles of moral rules and the systems they comprise.
- * Ethical principles involve the following:
 - * Autonomy i.e. the right to make one's own decisions.
 - * Beneficence i.e. doing the right thing, showing compassion, helping others.
 - * Nonmaleficence i.e. avoiding doing any harm.
 - * Justice i.e. being fair in the distribution of benefits and risks.

Corporate Compliance Programs

- * A program implemented by healthcare institutions to detect and prevent noncompliance with applicable government laws and regulations. The program is made up of seven elements:
- * The first element is written policies and procedures.
- * The second element is a designated compliance officer and compliance committee to oversee the program.
- * The third element is effective training and education.

Corporate Compliance Programs (con't)

- * The fourth element is an open line of communication e.g. a hotline to report potential compliance violations.
- * The fifth element is enforcement through disciplinary policies, processes, and guidelines.
- * The sixth element is an auditing and monitoring program to detect compliance violations.
- * The seventh element is the use of corrective action plans for violations.

Sarbanes Oxley Act

- * Sarbanes –Oxley Act of 2002 was passed as a response to corporate public company scandals such as Enron, World Com, and Tyco (HealthSouth in healthcare).
- * To improve the accuracy and reliability of corporate disclosures as well as protect investors, the Act includes such provisions as:
 - * Requiring top executives e.g. CEO and CFO to stand behind the financial reports of their companies.
 - * Continuously searching for conflicts of interest.
 - * Establishing a public company accounting oversight board.
 - * Providing protection for whistleblowers.
 - * Requiring policies and procedures for auditor independence.
 - * Public reporting of CEO and CFO compensation.

Antitrust Laws

- * The Sherman Antitrust Act of 1890 prohibits monopolies or unreasonable combinations of companies or restraints of trade. Applies the rule of reason standard to determine violations but some violations can be per se. Plaintiffs must prove relevant geographical or product market. Authorizes treble damages for violations.
- * The Clayton Act of 1914 defines and prohibits unethical business practices such as price fixing, monopolies, and upholds various rights of labor. Provides safety zone for older hospitals, less than 100 beds or 40 patients. Enforcement agencies apply the Herfindahl-Hirschman Index in determining antitrust violations.

Antitrust laws (con't)

- * Federal Trade Commission Act of 1914 created the Federal Trade Commission (FTC). The FTC is one of the two federal authorities who pursue antitrust violations along with the Department of Justice. The Act outlawed unfair acts, methods or deceptive practices to foster fair competition and protect consumers against unfair trade practices.
- * Robinson-Patman Act of 1936 prohibits anti-competitive practices including price discrimination.

Medicare

- * Medicare Part A: Health Organizations Insurance (HI)
- * Medicare Part B: Supplementary Medical Insurance (SMI)
- * Medicare Part C: Medicare Advantage Plans
- * Medicare Part D: Prescription Drug Coverage

Medicare Eligibility

- * Be 65 years old.
- * Be under 65 years old, permanently disabled, and receive Social Security Disability Benefits.
- * Be under 65 and have end Stage Renal Disease.
- * Be under 65 and have Lou Gehrig's Disease.
- * Public Health Hazard.

Medicare Part A

- * Mandatory Program
- * Financed by special payroll taxes paid equally by employers and employees.
- * Covers inpatient hospitalization.
- * Covers skilled nursing care facility care.
- * Covers home health care visits.
- * Covers hospice services.

Medicare Part B

- * Voluntary Program
- * Financed partly by general tax revenues and partly by required premium contributions from the beneficiaries.
- * Covered services includes physician, ambulance, outpatient services, emergency room visits, outpatient rehabilitation, dialysis services, prostheses, medical equipment, supplies, Part B drugs, and some home health services not connected to an inpatient hospital or SNF stay.
- * Premiums are income based.

Medicare Part C

- * Alternative to the traditional Medicare Program as it combines requirement of Medicare Part A, Part B, and Part D.
- * Coverage for services offered through private health plans.
- * Part C plans include a limit on out of pocket costs for covered services.
- * Plans generally paid on a capitation basis.

Medicare Part D

- * Voluntary and operates through Contracted Private Insurers.
- * Program subsidized particularly for low income beneficiaries.
- * Coverage Gap contains a Donut Hole.
- * Coverage includes most FDA approved Prescription Drugs and Biologicals.
- * Beneficiaries can enroll in stand alone Prescription Drug plan or Integrated Medicare Advantage Plan.

Medicaid Program

- * Statutory authority is Title XIX of the Social Security Act.
- * Largest source of medical & health related services for nation's poorest people.
- * Joint federal-state match funded program.
- * Program varies by state.
- * States may change eligibility, coverage, or reimbursement at any time.

Ethics in Patient Referral Act i.e. Stark Law

- * The Stark Law prohibits physicians from referring patients for certain designated health services paid for by Medicare to any entity in which they have a “financial relationship”. Financial relationship” is broadly interpreted to include any direct or indirect ownership or investment interest by the referring physician, as well as any financial interests held by any of the physician’s immediate family members.

Stark Law Elements

- * A referral
- * By a physician
- * Of a Medicare or Medicaid patient
- * For a designated health service
- * To an entity
- * With which the referring physician has a financial relationship

Stark Law General Structure

- * Goal of the law is to avoid over-utilization of specific services.
- * Designated Health Services are numerous including such services as inpatient and outpatient hospital services, lab services, physical therapy, occupational therapy, lab services, radiology services, etc. (spelled out in Stark I and Stark II regulations).
- * 35 exceptions such as bona fide employment relationship, fair market value compensation, rental of office space, etc.
- * Civil statute

Antikickback Statute

- * The statute prohibits the exchange of remuneration broadly defined as anything of value for referrals for services that are payable by a federal program i.e. Medicare and Medicaid.
- * The Act includes two exceptions (disclosed discounts and bona fide compensation) and several safe harbors.
- * Includes a “knowing” or “intent” requirement.
- * It is a criminal statute.
- * Violation of Antikickback Act also constitutes a False Claims Act.

Antikickback Statute Elements

- * Knowingly
- * Solicits or Receives
- * Remuneration
- * In return for a referral
- * For which payments made in whole or part by Medicare or Medicaid.
- * No safe harbor applies

Safe Harbor Examples

- * Referral services
- * Personal services and management contracts
- * Equipment rental
- * Space rental
- * Investment interests
- * Sale of Practice between practitioners
- * Warranties
- * Discounts
- * Waiver of coinsurance
- * Electronic Medical Record

False Claims Act (FCA)

- * The FCA , initially passed in 1863, provides that any person is liable to the United States government for civil penalties of \$5,500 to \$11,000 plus treble damages (as well as criminal penalties possible), if he or she:
 - * 1) Knowing presents or causes to be presented, to an officer or employee of the U.S. Government.
 - * 2) Knowingly makes, uses, or causes to be made a false record or statement to get a fraudulent claim paid or approved by the U.S. Government.
 - * 3) Conspires to defraud the government to get a fraudulent claim paid.
 - * 4) Knowingly makes, uses, or causes to be used a false statement to conceal an obligation to pay the government.

FCA (con't)

- * For purposes of the Act “knowingly” means:
 - * 1) Has actual knowledge of the information.
 - * 2) Acts in deliberate ignorance of the truth or falsity of the information.
 - * 3) Acts in reckless disregard of the truth or falsity of the information.
 - * 4). No proof of specific intent to defraud is required.

FCA (con't)

- * The HHS Office of Inspector General (OIG) and the U.S. Department of Justice (DOJ) can investigate FCA violations allegations.
- * DOJ brings a lawsuit on behalf of the U.S. Government.
- * The FCA includes “Qui Tam” i.e. whistleblower suits.
- * The OIG puts out an annual work plan which targets areas of interest for potential investigations.
- * The OIG also puts out fraud alerts, advisory opinions, and compliance plan guidance.

Emergency Medical Treatment and Active Labor Act (EMTALA)

- * EMTALA was passed in 1986 to prevent Medicare – participating hospitals from dumping patients out of emergency departments (also called antidumping law).
- * The law requires hospital emergency rooms are subject an appropriate medical screening requirement to determine whether the individual has an emergency medical condition.
- * Additionally, if an emergency medical condition exists, the hospital must stabilize the individual before transferring the individual.

Other Laws/Regulations

- * Medicare Conditions of Participation are the requirements hospitals, must meet to participate in the Medicare and Medicaid program. Their intent is to protect patient health and safety and ensure quality of care is provided to all patients.
- * Interpretative guidelines are provided by CMS to define or explain relevant provisions but do not provide new requirements.
- * The similar requirements for skilled nursing facilities and nursing facilities.
- * Joint Commission certifies and accredits healthcare organizations and programs.
- * Joint Commission Accreditation is required as part of the conditions of participation.
- * Accreditation is certification process by a private professional body of an educational program to obtain and retain accreditation through the evaluation of the body's established criteria.

Conflicts of Interest

- * A situation in which the concerns or aims of two different parties are incompatible or in which the individual has competing loyalties.
- * In health care at times there may be a conflict between the financial interest of the physician and/or organization and the best interests of the patients.
- * Additionally, gifts from drug or medical device companies to physicians to influence drug/device use or selection may create conflicts of interest.
- * Several laws may recognize the problem with (COIs) such as the Stark exception limitation regarding incidental gifts.

Employment Law

- * Civil Rights Act of 1964 (Title VII) which was amended by the Equal Employment Opportunity Act of 1972, prohibits discrimination based on race, color, religion, sex, or national origin.
- * The American with Disabilities Act of 1990 protects the rights of the disabled by prohibiting job discrimination in hiring, promotion, and other requirements of employment against qualified individuals with disabilities.

Employment Law (con't)

- * Age Discrimination in Employment Act of 1967 addresses age discrimination.
- * The Family and Medical Leave Act of 1993 grants temporary (i.e. up to 12 workweeks of unpaid leave during any 12-month period) medical leave to employees under certain circumstances e.g. birth of a child or care of an immediate family member.
- * Pregnancy Discrimination Act guards against discriminating against employees based on her pregnancy or intended pregnancy.

Employment Law (con't)

- * The Equal Pay Act prohibits sex discrimination in the payment of wages.
- * The Fair Labor Standards Act established minimum wages and maximum hours of employment.
- * Wrongful Discharge can be retaliatory or constructive (e.g. for whistleblowing).
- * Sexual harassment (Title VII and EEOC) defines the term as unwelcome sexual advances, request for sexual favors, and other verbal or physical conduct of a sexual nature when the conduct explicitly or implicitly affects employment.

Torts

- * A tort is a civil wrong committed against a person or property for which a court provides a remedy.
- * The categories of torts include negligence, intentional torts and strict liability.
- * Malpractice is negligence committed by a professional in his or her professional capacity.
- * The elements of a negligence claim are duty of care, breach of duty, injury, and causation. Injury must be foreseeable from breach.

Torts (con't)

- * Intentional torts include assault, battery, false imprisonment, defamation of character (libel or slander), fraud, invasion of privacy, and infliction of mental (emotional) distress.
- * Strict liability theory holds the defendant responsible for certain damages caused by their actions or products regardless of fault on their part.
- * Products liability is liability of a manufacturer to a buyer for injuries sustained due to a defect in a product.

Torts (con't)

- * Defenses to negligence include contributory negligence, comparative negligence, assumption of the risk, borrowed servant, captain of the ship, intervening cause, sovereign immunity, statute of limitations, and Good Samaritan statute.
- * Corporate negligence holds the hospital liable if it fails to uphold the proper standard of care owed the patient, which is to ensure the patient's safety and well-being at the hospital.
- * Respondeat Superior holds employees liable, given the circumstances, for the wrongful acts of their employees.
- * Res Ipsa Loquitor shifts the burden of proof in a negligence case from the plaintiff to the defendant.

Administrative Law

- * Certificates of Need is a permit granted by a governmental body which gives a healthcare institution permission for construction and modification of health agencies, major equipment expenditures, or new health services.
- * Treatment IND is a FDA approved treatment with an investigational new drug outside of clinical trials, used when the drug is for a serious or immediately life threatening disease and no effective alternative drug is available.

Administrative Law (con't)

- * Licensure refers to the granting of a licensure by a governmental body to an organization e.g. hospital, nursing home, and health plans or individuals e.g. physician, nurse, nurse practitioner, pharmacist, etc. requirements are usually spelled out within state statutes.
- * Occupational Safety and Health Act is a law passed by Congress to establish and enforce standards for occupational health and safety. Standards developed for various industries are mandatory for all covered employers.

Informed Consent

- * Informed Consent requires the patient to be informed of the potential risks, benefits, and alternatives of a proposed procedure.
- * Must be in language that is clear and understandable.
- * Cannot require the patient to waive any rights or to release the provider from liability.
- * States required courts to either use the objective standard resolves an informed consent issue by determining what a reasonably prudent person would have done when informed of the risks, benefits, and alternatives of a procedure or the subjective standard which resolves whether informed consent was given through the patient's testimony.

Types of Consent

- * Written Consent
- * Oral consent
- * Implied Consent
- * Statutory Consent
- * Judicial Consent

Patient Rights

- * Some patient rights include the following:
 - * Right to an explanation of their rights.
 - * Right to treatment without discrimination based on race, color, religion, sex, national origin, disability, sexual orientation or source of payment.
 - * Copy of medical record information.
 - * Receive an itemized bill a explanation of charges.
 - * Receive all information which would allow them to provide informed consent.
 - * Complain without fear of reprisal about the care they received.
 - * Received an accounting of PHI disclosures.

Health Care Quality Improvement Act

- * Health Care Quality Improvement Act (HCQIA) places limitation on damages for professional review actions that are conducted in accordance with the safe harbor requirements of the statute.
- * The statute provides immunity from legal damages if the following requirements are met:
 - * Professional actions were taken in the reasonable belief that the actions were taken in furtherance of quality health care.
 - * Professional actions were taken after a reasonable effort to obtain the facts of the matter.
 - * Professional actions were taken after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances.
 - * Professional actions were taken in the reasonable belief that the action was warranted by the facts.

Credentialing

- * Credentialing involves the process of determining eligibility for hospital medical staff membership and/or privileges to be granted to providers due to their academic preparation, licensing, training, and performance.
- * Economic Credentialing involves decisions about the medical staff appointment and/or clinical privileges of a practitioner that take economic factors into account e.g. lengths of stay, number of tests ordered.
- * Fiduciary Credentialing involves a loss of hospital privileges based on a physician's economic competition with a hospital.

Tax Exemption Issues

- * Not for Profit hospitals and other not for profit healthcare institutions have traditionally been considered charities under state law.
- * IRC Section 501 (c) 3 status provides exemption from federal and state taxes and acceptance of charitable donations.
- * Inurement is prohibited but private benefit is acceptable if incidental to charitable activity.
- * Other issues include:
 - * Unrelated Business taxable income
 - * IRS Intermediate Sanctions
 - * Revenue Ruling 98-15 involves two prong test for joint ventures i.e. purpose and control tests.

Credentialing (con't)

- * Negligent Credentialing is a legal doctrine based on the idea that the hospital has a duty of care in the selection of its medical staff.
- * Some credentialing documentation should include:
 - * State license
 - * Controlled Substances Registration (if required)
 - * Professional liability insurance
 - * References
 - * Board certification (if applicable)
 - * Photo identification
 - * Background Checks

End of Life Legal Documents/Principals

- * Advance Directives are instructions by individuals specifying what actions should be taken for his or her care .
- * Living will is a legal document describing those treatments the individual does not wish to receive if he or she is incapacitated or unable to communicate.
- * A healthcare proxy allows a person to appoint a health care agent to make treatment decisions if he or she becomes incapacitated or is unable to make decisions for him or herself.
- * A durable power of attorney allows an individual to give another person the authority to act on their behalf.
- * Guardianship involves the Court declaring a person incompetent and appointing a guardian.
- * Surrogate decision maker is an agent who acts on the behalf of an individual who lacks capacity to participate in a particular decision.

References

- * These slides were based on the publications listed below:
- * *Legal Aspects of Health Care Administration*, Thirteen Edition, George D. Pogzar, Jones and Bartlett (2019).
- * *Problems in Health Care Law, Challenges for the 21st Century*, Tenth Edition, John E. Steiner, Jr., Jones and Bartlett (2014).
- * *Legal and Ethical Issues for Health Professionals*, Fifth Edition, George D. Pozgar, Jones and Bartlett (2020).
- * *Health Care Management and The Law*, Second Edition, Donna K. Hammaker and Thomas M. Knadig, Jones and Bartlett (2018).