

## FUNDAMENTALS OF HEALTH LAW

### INTRODUCTION TO HEALTH CARE LAW

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## HEALTH CARE INDUSTRY

- Heavily regulated
- Political "Hot Potato"
- Economically challenged
- Changing rapidly



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## ECONOMICS OF HEALTH CARE

- Unusual Market
- Who is the "Buyer?" - Patient, Doctor, Managed Care Organization ("MCO"), Employer /Government?
- Oddly organized distribution system. "Seller" - hospital, doctor, SNF, HHA, ancillary provider, PPO/MCO, ACO



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## REIMBURSEMENT SYSTEM

- From reasonable costs and usual charges to negotiation or pre-set rates (often below costs)
- Fee for service, capitation, DRGS, time periods, pay for performance
- Not aligned interests – e.g. Dr./hospital
- Bundling/Unbundling



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## REIMBURSEMENT SYSTEM



- Financial pressures mount (drug costs, physician and nursing shortages, new technologies competition from specialty providers, malpractice, pension funding)
- 2003 Medicare Prescription Drug Act
- Mandated services without compensation – e.g. EMTALA

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## CORPORATE NEGLIGENCE

- Direct liability of individual provider
- Vicarious liability of individual provider and/or facility
- Corporate negligence (direct liability) of hospital  
*Thompson v. Nason Hospital*, 527 PA. 330, 591 A.2d 703 (1991)
- HMOs may be liable to patients under theories of both vicarious liability and/or direct corporate liability
- The corporate practice of medicine doctrine
- Applicability to nursing homes being litigated now

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**Thompson v. Nason Hospital, 527 Pa. 330, 591 A.2d 703 (1991)**



- In Pennsylvania, the Hospital has a duty to:
  - Use reasonable care to maintain safe and adequate facilities and equipment
  - Select and retain only competent physicians
  - Oversee the patient care rendered by all persons who practice medicine within its walls
  - Formulate, adopt and enforce adequate rules and policies to ensure quality care

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**FAIR SHARE ACT**

- Pennsylvania adopted the Fair Share Act on June 28, 2011.
- The Act provides that defendants who are found to be less than 60 percent at fault in negligence actions only will be subject to liability for their share of the responsibility for the loss.



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**ENFORCEMENT AGENCIES**



<u>Federal</u>	<u>State</u>
HHS FDA	DOH
CMS IRS	PID
OIG	DPW
OCR	MFCU
DOJ	
FTC	

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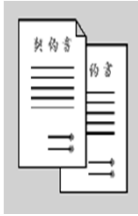
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## LICENSURE/CREDENTIALING



- Licensure and credentialing occur at both the State and Federal levels
- State agencies involved
  - Department of Health
  - Department of Public Welfare
  - Department of Insurance
  - Department of State

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## LICENSURE/CREDENTIALING (Cont.)

- Federal Oversight
  - Medicare/Medicaid
  - National Practitioner Data
  - Accrediting Bodies
    - The Joint Commission
    - NCQA
    - URAC

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## PEER REVIEW

### THE PENNSYLVANIA PEER REVIEW PROTECTION ACT, 63 PA. STAT. §425.2

Defines peer review as: “[T]he procedure for evaluation by professional health care providers of the quality and efficiency of services ordered or performed by other health care providers...”



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**PEER REVIEW  
(Cont.)**

THE HEALTH CARE QUALITY  
IMPROVEMENT ACT, 42 U.S.C. §11151 et seq.

Defines professional review as: “An action or recommendation of a professional review body... based on the competence or professional conduct of an individual physician (which conduct affects or could affect adversely the health or welfare of a patient...), and which affects (or may affect) adversely the clinical privileges... of the physician.”

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**PEER REVIEW  
(Cont.)**

- NEW JOINT COMMISSION CREDENTIALING STANDARDS, Effective January 1, 2004
- November, 2004 – Guidance clarifies that all practitioners who provide medical care in the hospital must be evaluated by the medical staff



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**Joint Commission Standard  
MS.01.01.01**

- The Joint Commission revised its accreditation standard regarding Medical Staff Bylaws to align with the Medicare Conditions of Participation.
- These changes included:
  - Specific requirements for inclusion in Medical Staff Bylaws
  - Definition of relationship between Medical Staff and Medical Executive Committee
  - Outline of Authority of Medical Executive Committee and Hospital Governing Body
- The standard went into effect on March 31, 2011.

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**HEALTH CARE QUALITY  
IMPROVEMENT  
ACT OF 1986 (HCQIA)**

- Provides Federal Antitrust immunity for peer review actions taken in accord with due process guidelines for the affected physician

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**LEGAL STRUCTURES**

- NON-PROFITS ARE COMMON
  - Federal and State tax exemptions (coming under increased scrutiny)
  - Attorney general oversight
  - Governing body responsibilities

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**LEGAL  
STRUCTURE/GOVERNANCE**



- Non-profit corporations
- For-profit corporations
- Professional corporations/limited liability companies
- Convergence of non-profit corporation law with business corporation law
- Application of the Sarbans-Oxley Act to healthcare organizations
- Compliance obligations- CAREMARK Case

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## FAILURES IN CORPORATE GOVERNANCE



- Conflict of interest
- Breach of duty of care and loyalty
- Board member or executive taking opportunity from the corporation
- Tortious interference with contract or business relationships

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## HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA) AND ITS PRIVACY AND SECURITY REGULATIONS

(45 C.F.R. PARTS 160 AND 164)

- Key concepts
  - Covered entities
  - Protected Health Information (“PHI”)
  - Treatment, payment and operations uses of PHI
  - Patient authorizations
  - Disclosure to business associates
  - Flexibility of approach to security



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## HITECH Act (American Recovery and Reinvestment Act of 2009)

- Encryption standards for electronic data
- Requires Covered Entities to notify patients when a breach of the HIPAA Privacy Rule has occurred, and the breach “compromised the security or privacy of the information”
- “Breach” defined as acquisition, access, use or disclosure of personal health information (“PHI”) in a manner not permitted by the Privacy Rule

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## STARK, ANTI-KICKBACK AND FALSE CLAIMS – "THE BIG 3"



- STARK – "Referral by doctor with a financial relationship" for "designated health services"
- Complexities abound
- Regulatory history

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## United States ex rel. Singh v. Bradford Regional Medical Center

- Stark Law issue raised in structuring acquisition of physician practice
- BRMC entered into sublease with physicians to lease nuclear camera
- Sublease included a non-compete agreement to prevent physicians from competing with hospital's nuclear imaging service
- BRMC paid physicians \$6,500/month for lease of camera and \$24,000 for non-compete
- Court found payments were in excess of FMV, took referrals into account and did not meet a Stark exception

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## ANTI-KICKBACK LAWS



- Federal and State
- GREBER – "1 Purpose" Test
- Penalties include "economic death penalty"
- Safe harbors

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## COMMON AREAS OF CONCERN

- Physician recruitment and service agreements
- Joint Ventures involving physicians (e.g. ASCs, specialty hospitals)
- Leases with doctors



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## FALSE CLAIMS ACT (FCA)

- "Lincoln Law"
- False statement/claim
- Federal payment
- "Reckless disregard" standard
- Qui Tam relators
- Severe damages
- Very scary



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## FCA AMENDED BY PATIENT PROTECTION AND AFFORDABLE CARE ACT OF 2010 (PPACA)

- Expand scope of FCA liability
- Make Anti-Kickback Law violation a false claim
- Liability for retention of overpayments
- New investigative tools for the government
- Expanded protection for "qui tam" relators (whistleblowers)

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## EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA”)

(EFFECTIVE AUGUST, 1986)



- Requires covered hospitals to provide a medical screening examination and necessary stabilizing treatment to any person who comes to the hospital requesting care and treatment for emergency medical condition

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## EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA”)

(Cont.)

- Purpose of EMTALA

- To prevent hospitals from “dumping” persons who are unable to pay for their treatment
- Significant revisions to EMTALA regulations were finalized by CMS in 2004
  - EMTALA does not apply to inpatients
  - No 24/7 Rule if three physicians in a specialty



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## COMPLIANCE PROGRAMS

- Compliance programs are a condition of enrollment in Medicare, Medicaid and the Children’s Health Insurance Program under Section 6401 of PPACA.
- Federal Sentencing guidelines reward providers with effective compliance programs with reduced fines and penalties
- OIG encourages compliance programs

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**OIG MODEL COMPLIANCE  
GUIDANCE: COMMON  
ELEMENTS**

1. Compliance as element of performance plan
2. Designation of Compliance Officer and Compliance Committee
3. Conduct effective compliance training/education
4. Develop effective lines of communication

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**COMMON ELEMENTS of  
COMPLIANCE (Cont.)**

5. Systematic Auditing/Monitoring
6. Enforcing Standards through publicized Disciplinary Guidelines
7. Responding to detected offenses and development of Corrective Action

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**SOME OIG COMPLIANCE  
GUIDANCES**

- Clinical Labs
- Hospitals
- Home Health Agencies
- Third Party Medical Billing Companies
- Durable Medical Equipment
- Nursing Facilities
- Individual and Small Group Practices
- Pharmaceutical Manufacturers

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## ACCOUNTABLE CARE ORGANIZATIONS (ACOs)

- Program to be established by Jan. 1, 2012
- ACOs are organizations of healthcare providers that collaborate to offer or arrange for all care among independent providers and provider groups
- PPACA established the Medicare Shared Savings Program that allows ACOs to serve Medicare fee-for-service patients

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## ACOs (Cont.)

- Purpose: To help providers form pro-competitive ACOs to benefit Medicare and private patients under a payment arrangement that allows providers to profit from reduced costs and improved quality
- Entity: Legal entity under state/federal law with one or more Medicare-enrolled healthcare providers or suppliers to receive and distribute payments for shared savings to participants (“Medicare Shared Savings Program”)

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## ACOs (Cont.)

- Requirements:
  1. Must have at least 5,000 Medicare fee-for-service beneficiaries
  2. Can be composed of: a) physicians/other health professionals in group practice; b) networks of individual practices and/or hospital; c) hospital employing professionals
  3. Requires processes to promote evidence-based medicine, patient engagement, and reports on quality, cost measures and care coordination

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## DOJ/FTC ANTITRUST POLICY STATEMENT ON ACOs

- On Oct. 20, 2011, the DOJ and FTC statement on antitrust enforcement policy- no mandatory antitrust review; voluntary reviews offered to ACOs that want to know if provider affiliations will run afoul of federal antitrust laws.
- Antitrust “safety zone” for certain ACOs with CMS approval.
- Policy does not cover state antitrust laws. 37

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## FEDERAL ANTITRUST LAWS



- Enforced in the healthcare industry by
  - The Federal Trade Commission
  - The Department of Justice Antitrust Division
  - Pennsylvania Attorney General Review

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## SPECIAL ISSUES FOR TAX- EXEMPT PROVIDERS

- No “private inurement” or impermissible “private benefit”
- Intermediate sanctions – personal penalties, “rebuttable presumption”
- FMV, disinterested directors, documentation



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