I. Introduction

A. Themes
   a. Historically - Doctors not challenged as decision-makers.
   b. Now - everything they do is subject to review
   c. Different approaches between medical and legal fields
      i. Doctors look at set of facts and look for rules
      ii. Lawyers begin with set of rules and look for determination of facts
   d. Concept of Health Care Rationing

II. The Provider-Patient Relationship

A. Doctor-Patient Relationship: Overview
   a. Medical terms
      i. Disease – something caused by a recognized organic process
      ii. Illness – set of symptoms (with or without an underlying disease process) that the prevailing society and culture accept as outside the normal range of everyday life.
   b. Healing – general phenomenon of healing through care or attention of physician.
   c. Fiduciary Nature of Relationship – principles impose special measure of loyalty and devotion on several classes of professionals by virtue of their control over an important subject matter, the vulnerability of their clients and the resulting potential for abuse.

B. Duty to Treat Patients
   a. Background Rule – consensual; both parties must agree, physician may refuse to accept patients.
      i. Limitations – traditionally, legal; now defined more often by private agreements among patient, insurance plan, and provider.
         1. Hospitals must stabilize patient’s condition in emergencies.
         2. Doctors and hospitals may not refuse patient for discriminatory reasons (race, sex, HIV-status).
         3. May not cease treatment without making proper arrangements.
         4. May not impose unreasonable conditions on agreement to treat.
   b. Duty to Accept
      i. Physician not obligated to provide care to particular individual unless they have agreed to do so, Hurley v. Eddingfeld [Physician does not have a legal duty to accept treatment of patient when no other physician is available and patient in dire need of treatment.]
         1. Limitations
            a. Some states requires limited duties on physicians to accept certain types of patients [Mass – to be licensed, physicians must agree to accept patients covered by Medicaid].
      ii. Hospitals
         1. Private Hospitals – Generally, no duty to accept patients
            a. Growing support for idea of “quasi-public” hospitals – would impose obligation on hospitals to treat based on idea that hospitals are “businesses affected with a public interest.”
         2. Emergency Rooms
a. If private hospital establishes emergency ward, duty to accept patients in emergency unit in the case of an unmistakable emergency. Wilmington General Hospital v. Manlove

b. Many states impose requirement of open emergency rooms by statute or regulation.

c. Hospitals may limit – if ER full, hospitals may alert ambulances not to stop.

d. Doctor on duty at ER voluntarily takes on hospital’s duty of care. Hiser v. Randolph

i. Similar analysis may be true of HMO physicians.

3. Duty to treat patients who cannot pay – regulations place some greater duties on hospitals, but these are limited and cannot be enforced by individuals.

a. Charitable tax exemption – non-profit hospitals are “charities” and are exempt from property and income taxes; part of status includes obligation to treat some patients for free. [usually restricted to ER patients].

i. Some states beginning to require hospitals to devote certain percentage of overall services to patients who cannot pay.

4. Duty to treat patients who can pay – common law and regulatory duties to treat these patients.

iii. Continuing Treatment - Once patient recovers from illness or stops seeking treatment, new treatment relationship must be formed to invoke duty of continuing treatment. [May be different where patient receives treatment from HMO.]

c. EMTALA

i. All hospitals that execute Medicare provider agreements with Feds must treat all patients who enter ER in accordance with the Emergency Medical Treatment and Active Labor Act [EMTALA].

1. Limitations – Duty only arises when patient arrives at ER and requests exam; hospitals may deny a transfer or divert an ambulance and avoid violations. Miller v. Medical Center of Southwest Louisiana

a. HHS Regulation suggests that hospitals may only divert where hospital does not have staff or facilities to accept any additionally ER patients. 42 C.F.R. §489.24

b. Ambulances – patients in ambulances owned and operated by hospital have come within care of hospital under meaning of EMTALA; if ambulance not owned by hospital, patient has not come into ER until reaching hospital grounds.

2. Duty does not always end with termination of ER treatment – where hospitals admit, and then transfer or discharge before full treatment, violation may exist. (Pregnant woman admitted, and then transferred several days later after labor began and there was evidence of fetal distress. Smith v. Richmond Memorial Hospital

3. EMTALA cannot be used to bring malpractice claims – some confusion about what is appropriate screening (where doctor may have only done cursory screening); courts generally look at whether
hospital screened patient in the same way it screens similarly situated patients. Any departure constitutes inappropriate screening.

ii. **Specific Duties:**

1. **Upon arrival at ER, requires appropriate screening exam with capability of hospital’s ER to determine if emergency condition exists or whether individual is in active labor.** 42 U.S.C. §1395dd(a)
   a. Hospitals obligated to apply uniform screening to all individuals coming to ER.
   b. Screening meant to prevent disparate treatment.

2. **Any person with emergency condition must be treated or stabilized before transfer in accordance with EMTALA.**
   a. Requirements for allowable transfer:
      i. Transfer allowable where patient requests, or physician certifies in writing that benefits outweigh risks of transfer.
      ii. Receiving hospital must be capable of providing needed care, and must have agreed to accept transfer.
      iii. Transfer must occur with appropriate personnel and transportation, including life support measures.
   b. Statutory language that transfer “may pose a threat” entitles women to EMTALA protection upon showing of possible threat, it does not require proof of reasonable medical probability that threat will come to fruition. *Burditt v. U.S. Dept. of Health of Human Services*

iii. **Statutes does not require showing that patients denied care because of indigency or lack of insurance;** therefore, courts have generally held that it is irrelevant why hospital denied screening.

iv. **No exception for futile care** – court refused hospital’s request for permission to deny care to infant based on the futility of improving her condition. Court held this qualified as a medical emergency. *In re Baby K*

C. **Formation, Limitation, and Termination of the Treatment Relationship**

a. **Formation**
   i. **Where physician had previous relationship with patient, and returned patient’s phone call for unrelated matter, no relationship formed.** *Clanton v. Von Haam* [However, different issue if physician made recommendation and patient relied on advice and believed a relationship was formed.]
   1. **Merely scheduling appointment does not create relationship.** *Weaver v. University of Michigan Board of Regents*
   ii. **Telephone conference between treating physician and second physician does not create patient-doctor relationship with the second physician;** relationship can exist where other persons contact physician on behalf of patient, but they must request physician provide some sort of service to patient to create a relationship. *Reynolds v. Decatur Memorial Hospital*
[malpractice requires a duty, breach of duty, injury proximately caused by breach, and resultant damages]

iii. Some courts avoid formation question, and find that physician owes duty of care to the extent of his involvement.

b. Limitations
   i. Liability – Hospital cannot require patients to sign release absolving hospital of all liability. *Tunkl v. Regents of the University of California*
      1. Some partial waivers allowed –
         a. Provision in HMO agreement requiring arbitration of disputes upheld (arbitration does not change standard of care, only process of dispute resolution). *Madden v. Kaiser Foundation Hospitals.*
         b. Patient insists on leaving hospital against medical advice, hospital may ask patient to sign waiver.
         c. Patient who insists on type of medical treatment for religious reasons may be asked to sign waiver.
         d. Patient participating in experiment.
   ii. Allowable limitations
      1. Particular specialty or geographic area
      2. Not obligated to prove care that offers no medical benefit.
      3. Conscientious Objection – Ob/Gyns opposed to abortion are protected against having to perform them.
   c. Termination
      i. Abandonment – physician may only abandon/terminate care after giving due notice and affording an ample opportunity to secure the presence of another attendant.
         1. **Issue – does termination only require notice, or that patient actually secure another physician? [Usual practice is for physicians to secure a substitute themselves to avoid liability.]**
      iii. May also end explicitly if patient unilaterally chooses to dispense with physician’s services or if both parties agree to the termination.
      iv. Non-payment – physician may not discontinue care for this reason; however, it is an acceptable basis for proper termination of the relationship.

D. Confidentiality of Medical Information
   a. Improper Disclosure
      i. Willfully disclosing confidential information means knowingly disclosing, not disclosing with the intent to cause harm to the patient. *Doe v. Marselle*
      ii. Most states provide private cause of action for patients against health care providers who impermissibly disclose confidential information obtained during course of treatment.
         1. Possible types of claims –
            a. Breach of contract
               i. Generally longer statute of limitations
               ii. Avoid some procedural barriers to malpractice suits established as part of tort reforms.
               iii. Standard of proof only that physician failed to honor degree of confidentiality promised.
                  1. Do not need to prove applicable standard of care in field.
            b. Malpractice
c. Breach of fiduciary duty
d. Act of fraud/misrepresentation
e. State statutes
   i. Questions presented by statutes:
      1. types of information protected from disclosure;
      2. who has the duty to maintain confidentiality;
      3. standard of care applied to determine a breach of duty;
      4. circumstances under which confidentiality may be breached;
      5. circumstances under which the duty terminates.

2. Other related issues
   b. Constitutional Right – several courts have found a constitutionally protected interest in maintaining privacy of medical information.
      i. Doe v. City of New York – individuals have constitutional right of privacy in their medical information; court employs balancing test to determine whether government’s interest in disclosure is “substantial” enough to outweigh the individual’s privacy interest.
   c. Confidentiality as a Rule of Evidence – patient communications protected under rules of evidence; prohibits discovery of protected information.
      i. Both physician and patient may invoke, but only patient may waive.
      ii. Privilege may only exist between physician and patient (e.g. one court held that privilege did not exist between patient and dentist).
      iii. Federal rules do not provide patient-physician privilege.
   d. Licensed health care providers may also face professional disciplinary action.
      iii. Exceptions – generally, where patient consents or where disclosure necessary to protect health and safety of either the patient or their parties.
   iv. Medical records
      1. Subject to confidentiality
      2. Patient access – health care providers deemed to “own” records; patients given right of access under state law within certain limitations.
      v. Additional concerns – advances in genetics create a greater ability to predict illness; individuals have interest in maintaining confidentiality of information while insurance providers and others have interest in gaining access to information.
   b. Mandatory Disclosure – most duties associated with risk or harm to others through criminal activity or transmission of disease. [example – must
disclosure knife and gunshot wounds to police, evidence of abuse, and AIDS status.]

i. Each state imposes disclosure obligations; typical statutes establish:
   1. who has the duty to disclose the information;
   2. the events or information that must be disclosed;
   3. the appropriate recipient of the disclosure; and
   4. the immunities or liabilities associated with the disclosure obligation.

ii. Types of disclosure duties – (generally, statutes protect confidentiality of information once it is reported)
   1. Evidence of abuse – stems from concerns that members of certain groups may not be able to communicate abuse to others
   2. Gunshot or knife wounds to police authorities
   3. Certain types of health-related information

iii. Immunities and liabilities
   1. Person who files report is usually immune from damages for any mistake or resulting harm.
   2. Failure to report may lead to civil or criminal liability.
      a. Courts divided as to whether children injured by failure to report may bring suit in jurisdictions where reporting statute does not include specific civil remedy.

iv. Common law duty
   1. Under theory that physician may owe duty to third party nonpatients based on physician’s negligence, a physician has a duty to inform nonpatients of risk of contracting disease where physician knows there is a high likelihood of contracting disease based on physician’s treatment of another. [requires a “special relationship” between physician and nonpatient]
   2. Cases indicate that the duty is established by a specific risk to foreseeable and identifiable third parties.

E. Informed Consent – Idea: requiring physicians to provide more information will help redress the power imbalance created by the inequality of knowledge.
   a. Standard of Care –
      i. Rules:
         1. Majority rule – “Professional Standard” – duty depends on whether it was custom of physicians in practicing community to make particular disclosure to patients; protects physicians from liability so long as they disclose what a reasonably prudent physician in similar circumstances would have.
         2. “Objective-Patient Centered Standard” –
         4. “Subjective-Patient Centered Standard”
      ii. Expert Testimony – Split as to whether expert testimony necessary to establish whether a physician has or has not complied with the standard of a reasonably prudent physician.
         2. Canterbury – expert testimony not necessary; lay witnesses will suffice
   b. Amount of Disclosure
i. Enough information to make intelligent choice; measured by patient’s need; all potential risks must be disclosed; objective standard. *Canterbury*

c. Duty limited to range of health care professionals; health care institutions do not have duty.
   i. Physician must disclose treatment alternatives if a reasonably prudent physician would have done so; some courts have extended this to disclosure of diagnostic techniques.
   ii. Physician must reasonably disclose possible risks or adverse side effects of treatment or non-treatment. *Canterbury v. Spence*
   iii. Must seek and secure consent before commencing operation or other course of treatment.

d. Elements of a Cause of Action – Plaintiffs must prove: (*Canterbury* – no causal connection unless disclosure would have resulted in patient’s decision against treatment; objective standard – what would reasonably person in patient’s position have done?; other courts have adopted a subjective standard)
   i. the medical procedure carried a specific risk that was not disclosed,
   ii. the reasonably prudent physician would have disclosed that risk to the patient,
   iii. the undisclosed risk materialized, and (*Rizzo*)
   iv. the failure to disclose the information caused the patient’s injury.

e. Obtaining consent
   i. Forms –
      1. Obtaining patient’s consent requires more than getting a signature on a generalized form. *Rizzo v. Schiller*
      2. Form indicating only that patient has received information and consents is probably not sufficient.
      3. Patient must have legal capacity to give consent.

f. Exceptions to Duty to Inform – (defendant generally has duty of proving exception present).
   i. Common knowledge – risks of which persons of average sophistication are aware.
   ii. Patient knowledge – risks already known to patient
   iii. Emergencies – where patient is incompetent (patient unconscious or otherwise incapable of consenting and harm from failure to threat is imminent and outweighs harm threatened by proposed treatment)
   iv. Therapeutic Privilege – where disclosure of risks presents serious threat of psychological detriment to patient (critical inquiry is whether physician responded to sound medical judgment that communication of risk information would present threat to patient)

g. Fiduciary Principles and Conflicts of Interest
   i. Principles from Fiduciary Relationship (Moore v. The Regents of the University of California)
      1. physician must disclose personal interests unrelated to the patient’s health, whether research or economic, that may affect the physician’s professional judgment; and
      2. physician’s failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duties.
   ii. There may be additional duties under ERISA schemes (*Shea v. Esensten*) – holding that patient had claim against health care organization when it did
III. Prevention of and Compensation for Adverse Medical Outcomes: Malpractice and Related Topics

A. The Problems of Medical Error
B. Contrasting Strategies for Reducing Medical Error
C. The Licensure of Medical Professionals
   a. AMA accreditation – most states require physicians to graduate from AMA accredited schools.
      i. AMA can control size of medical school class through accreditation process.
      ii. Creates a state-sanctioned monopoly.
   b. Licensure
      i. “Medical practice” – Court found person guilty of practicing medicine without a license where he administered mild electric shocks, prescribed natural vitamins, and accepted donations for his treatments; even where he never advertised nor described himself as a doctor, would sometimes recommend his customers to consult licensed physicians, and only met with people in his home. Court found that defendant’s actions amounted to diagnosing and treating patient’s ailments. *State v. Miller*
         1. Other treatments held to constitute practice of medicine: magnetism, mental suggestion, faith healing, color wave therapy, reflexology, massage, hypnotism, tattooing, and electrical hair removal.
         2. Activities outside medical practice: ear piercing and cosmetic hair removal.
      ii. Criminal Offense – Unlicensed practice of medicine is a criminal offense.
         1. Licensed health care providers subject to professional discipline, such as license revocation or suspension, for assisting in unlicensed practice of medicine.
   c. Licensure vs. Credentialing – Licensure statutes theoretically provide an absolute barrier to provision of some services by unlicensed persons. While, a certification scheme would allow consumers to choose care from an unaccredited or uncertified person.
   d. Regulation
      i. Health Care Quality Improvement Act established a centralized data bank that collects information about:
         1. disciplinary actions from all states,
         2. malpractice settlements, and
         3. negative hospital privileges determinations.
      ii. Failures in self-regulation
         1. Boards do not have adequate staff to respond to volume of complaints and to conduct extensive investigations of unprofessional conduct.
   e. Defenses
      i. Vagueness – courts have upheld statutes against vagueness charges.
      ii. Right to provide care – courts have rejected constitutional claims to the right to provide care. Courts uniformly uphold as long as regulations are rationally related to serving some legitimate state interest.
1. Statute rationally related that prohibited anyone but optometrists or ophthalmologists to fit glasses, even though it effectively prohibited opticians from replacing broken glasses. *Williamson v. Lee Optical of Oklahoma, Inc.*

iii. Religious exceptions – states often provide statutory exceptions for religious reasons.

iv. Right to receive treatment – most courts have found no fundamental right of access to treatment by unlicensed providers.

v. Physician delegation –

1. Nurses – traditionally, performed wide range of functions, sometimes under control of physicians and sometimes exercising independent judgement.
2. Physician assistants – dependent practitioners, only perform tasks delegated by physicians.
3. Some legislatures have enacted statutes that specifically allow physicians to delegate, but hold physicians ultimately responsible for medical acts of others.
4. Medically underserved areas – some states allow for even more delegation in areas with few or no physicians.
   a. Physicians’ assistants/nurses performing delegated tasks do so according to physician’s orders, standing medical orders, standing delegation orders, or written protocol.
   b. Some states have defined necessary supervision in terms of periodic physician reviews (e.g., daily status reports, one a week on site direction, etc.) and by limiting the number of people a physician can supervise.

D. Medical Malpractice: must show breach of: (1) the applicable standard of care, (2) breach of that standard of care by the defendant, (3) injury, and (4) proximate causation between the alleged breach and the injury.

a. The Custom-Based Standard – idea that there is a uniform/correct standard of care to which physicians should be held.
   i. Where defendant physician stated that she used the wrong needle during surgery, the court held that the statement did not make a prima facie showing that she violated the applicable standard of care. Plaintiff should have provided expert testimony as to the applicable standard of care. *Locke v. Pachtman*
   ii. Courts look to customary practices of medical profession as benchmark of acceptable behavior.
   iii. Criticisms – many commentators do not believe a standard exists. (Idea that standard of care is simply personal opinion/preference.)

b. Variations on the Custom-Based Standard
   i. Two schools doctrine – medical practitioner has an absolute defense to a claim of negligence when it is determined that the prescribed treatment or procedure has been approved by one group of medical experts even though an alternate school of thought recommends another approach, or it is agreed among experts that alternative treatments and practices are acceptable. Applicable only where there is more than one method of accepted treatment of procedure.
2. Pennsylvania court accepted “considerable number” standard. Did not define exact number – burden of showing a second school exists falls on the defendant. [Expert need only state factual reasons to support claim that there is a considerable number of physicians who agree with treatment method.] Jones v. Chidester

ii. Same locality rule – restricts geographical area from which the degree of care exercised by a physician or surgeon could be determined to the community in which the doctor resided.
   1. Many jurisdictions follow national rule.
   2. Some hold G.P.s to same/similar community rule, and specialists to national rule.
      a. Specialist vs. general practitioner – where procedure fell within purview of both specialist and general practitioner, court held g.p. to same or similar community rule. Chapel v. Allison

iii. Medical experiments – most modern courts use standard of reasonable experimentation; innovation must be for therapeutic reasons, not purely research curiosity.
   1. Most researchers employ informed consent to avoid liability. Sufficient to disclose:
      a. risks of the experimental therapy,
      b. fact that this is an experiment, or also
      c. comparative risks and benefits of the alternative.

iv. Unorthodox medicine – not many cases; however, court did not find malpractice where patient fully consented to treatment. (Another case found physician engaged in unprofessional conduct.)

   c. The Ordinary Negligence Standard
      i. Standard of care met – Where physician met ordinary standard of care, but did not employ a readily understandable procedure, trier or facts allowed to weigh relative risks of omitting or employing procedure. Helling v. Carey (highly criticized case)

   d. The Role of Experts in Litigation
      i. Opposing counsel may crs-ex expert as to how much they make as expert witness, and how often they testify. Trower v. Jones

      ii. Non-physician experts – courts split

      iii. Physician experts –
         1. Against physicians – Most courts do not require physician experts to practice in precisely same specialty as defendant.
         2. Against non-physicians – courts split; some courts allow physicians to testify against nurses, another court would not allow orthopedic surgeon to testify against podiatrist.

      iv. Geographic dimension – where jurisdiction follows local or state-wide standard of care, most courts to not require expert to actually live and practice in location.
         1. Courts allow experts to assert knowledge of local practice through professional contacts in addition to actual practice.

      v. Statutory reforms – some states are demanding more qualifications for experts. Examples – requiring expert
         1. to reside in or near the state;
         2. to have been in active practice in recent years (which excludes full-time teachers and researchers as well as “consultants”);
3. to practice in the same or overlapping specialty, or to have performed the same type of procedure, in recent years; and/or
4. to be licensed in the same professional category.

vi. Written sources – learned writings [e.g., medical books, treatises, etc.], when offered to prove the truth of the matter asserted, are hearsay. *McCourt v. Abernathy*

1. Modern trend – to allow testimony from learned treatises that the expert acknowledges are reliable; may not be received as exhibits but only read into evidence.
2. EXCEPTION – Package inserts for prescription drugs that contain FDA-required warnings and instructions for use. These written guidelines are directly admissible as independent evidence on the standard of care under the hearsay exception for tabulations, lists, and directories generally relied on by persons in particular occupations.

e. The Importance of Proving Causation – “Loss of Chance”

i. Traditional test – “more likely than not” – expert testimony must establish “reasonable possibility” rather than “probability” that doctor’s actions reduced life.

ii. Reducing chance of survival – court found, where medical testimony claimed that defendant’s actions reduced decedent’s chance of survival from 39 percent to 25 percent, evidence was sufficient to allow the proximate cause issue to go to the jury. *Herskovits v. Group Health Cooperative of Puget Sound*

f. Statutory Reforms

i. Caps for recovery – court upheld statutory cap on nonpecuniary losses at $250,000. *Fein v. Permanente Medical Group*

ii. See table, page 541 for reforms 1970s – 1980s

g. Hospital Liability

i. Vicarious liability – institution held strictly liable for acts of negligence by member physicians, based on the physician’s relationship with the institution.

1. Charitable hospitals – not liable for physician’s wrongdoing except because:
   a. implied waiver – person who accepts charity exempts benefactor from liability, and [Charitable immunity no longer exists; some states limit recovery amounts from nonprofit hospitals]
   b. relationship between hospital and physician – physician is analogous to independent contractor. *Schloendorff v. Society of New York Hospital*

2. Respondeat superior revisited – the Bing court rejected Schloendorff and held that, in certain cases the doctrine of respondeat superior may serve to render a hospital liable for the negligent acts of the medical personnel who deliver its service to its patients.

   a. Which cases?
      i. Brown applied respondeat superior where (1) the patient in the case sought treatment primarily from the hospital, and (2) the hospital paid the doctor a salary.
ii. Not applied where patient contacts personal physician and is admitted by him to the hospital for treatment.

iii. Other variations – court examined relationship between hospital and physician.

3. Ostensible agent theory – where physician not actual agent of hospital may still bind the hospital. Court applied theory where: (1) treatment took place in clinic, (2) clinic chose the physician, and (3) clinic billed on its stationary for physician’s charges. Howard

   a. Reliance – Usually requires showing that injured part detrimentally relied on the representation of agency.

      i. If applied in strict “but-for” fashion, almost impossible to show because few patients would refuse treatment if they knew doctors were independent contractors.

      ii. Most courts apply in more psychological terms, holding it sufficient that patient subjectively relied on hospital to render treatment and expected doctors to be employees. [Not necessary to show alteration in plaintiff’s behavior.]

   b. Enterprise liability - “Inherent function of the hospital” – where physician performing inherent function hospital could not do without (e.g., emergency room physician) court may apply respondeat superior. Adamski v. Tacoma General Hospital [courts have only applied in emergency room situations]

      ii. Direct liability – depends on showing some wrongdoing by the institution’s management with respect to physician competence and patient care.

h. Managed Care Setting

E. Regulation of Drugs and Medical Devises

F. Products Liability – Drugs and Medical Devises – follows strict liability (injured party need not prove that manufacturer of product that caused injury was negligent; focuses on product, holds manufacturer liable if product was defective.)

   a. Types of defective products:

      i. Flaw in manufacturing process, resulting in product that differs from manufacturer’s intended result.

      ii. Defect in design – perfectly manufactured products that are unsafe because of the absence of a safety device.

      iii. Lacks adequate warnings – products that are dangerous because they do not contain adequate warnings.

   b. Drugs – Liability attaches only if a manufacturer fails to warn of dangerous propensities of which it was or should have been aware. Brown v. Superior Court

      i. Drug manufacturers should not be subject to strict liability because they might be reluctant to research new drugs.

      ii. Manufacturers are required to continually monitor their drugs, and to change warnings if different risks materialize; the duty to warn is absolute and is not judged by reasonableness.

   c. Medical Devises – most courts do not distinguish, and refuse to apply strict liability to devises as well.
d. Hospital and Physician liability – no strict liability applies ONLY to design and warning defects.
   i. Manufacturing defects – strict liability applies to manufacturers and distributors, but not to physicians or hospitals so long as product was not altered by the provider.
   ii. Hospitals usually not strictly liable for products used directly for patient care (e.g., pacemakers), but can be held liable for failing to reasonably inspect and maintain equipment and medical devises.

e. Blood transfusions – most states have “blood shield” statutes declaring that blood products are not subject to strict products liability. [often to human organs and tissue transplants]

IV. The Business of Health Care

   A. ERISA Preemption
      a. ERISA’s roles:
         i. Supersedes any state law that “relates to” an employee benefits plan.
            1. Very broad interpretation
            2. Saves from preemption – states laws relating to banking, investing, and insurance.
            3. Exception – self-insured employee benefit plans are not deemed insurance plans, so they are exempt from state regulation. [Insurance has three part test:]
               a. whether the practice has the effect of transferring or spreading a policyholder’s risk;
               b. whether the practice is integral part of the policy relationship between insurer and the insured;
               c. whether the practice is limited to entities within the insurance industry.
         ii. Case law – Interpreted to preempt state jurisdiction and remedies with respect to employee benefit plans. (Allows defendant employee benefit plans to remove to federal court even where plaintiff only plead state claim in petition.)
         iii. Permits participant or beneficiary to sue to recover benefits “due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan.” (Forecloses traditional state suits, but federal suits are becoming more common.)
         iv. Imposes substantive requirements on employee benefit plans.
            1. Fiduciaries have obligation to act in interest of beneficiaries.
            2. Beneficiaries must receive a description of their rights.
            3. Beneficiaries who are denied must receive adequate notice, specific reasons, and a reasonable opportunity for review by the fiduciary of the denial.

   B. Basic State and Federal Regulation of Health Care Facilities
      a. Faculty Regulation
         i. Licensure – mandatory governmental process whereby a health care facility receives the right to operate. Operates on a state-by-state basis.
1. Licensed health care facilities: hospitals, nursing homes, ambulatory surgery centers, freestanding emergency centers, pharmacies, and in some instances, diagnostic centers.

2. Jurisdictional issues: (usually, must simply ask the governing authorities – statute are unclear; some issues covered by statute [i.e. freestanding emergency centers are beginning to have licensing requirements]

   a. Does a license for a central facility such as a hospital cover satellite facilities such as urgent care centers, or must the be separately licensed?

   b. Can specialty clinics be treated as doctor’s offices, and therefore not require a license?

   c. Does an existing license cover the buyer or lessor of the facility?

ii. Accreditation – private voluntary approval process through which a health care organization is evaluated and can receive a designation of competence and quality.

   1. Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) – does most of the private accreditation; governed by the major trade associations, primarily the AMA, American Hospital Association, etc.

   iii. Certification – voluntary procedure for health care organizations to meet the qualifications for participation in government funding programs, specifically Medicare and Medicaid.

b. Certificate of Need regulations – to open a new hospital, company must apply to state agency and make showing of need. Application can be challenged, and if approved, is subject to review by independent agency.

C. Issues Involving Nonprofit and Tax Exempt Status

   a. Doctrines of Nonprofit law:

      i. ultra vires or charitable purpose – all assets of a corporation organized solely for charitable purposes must be deemed to be impressed with a charitable trust by virtue of the express declaration of the corporation’s purposes.

         1. law does not require hospitals to run until they go broke; may wind-up operations and transfer ownership entirely to new corporation.

      ii. duty of care/business judgment rule – strict application regarding NPs.

      iii. duty of loyalty and conflict of interest –

b. Tax Exempt Status

   i. Integrated Delivery System – contain hospitals, nursing homes, etc.

      1. Tax exempt status approved for network parent that controlled system as a whole, and not necessarily for its component members. Important factors:

         a. Network included prominent teaching hospital;

         b. Network clinics would accept indigent patients in immediate need of care;

         c. Governing board drawn from general community, 20 percent limit on physician board membership.

   2. De facto requirements for tax exempt status:

         a. 20 percent limit on physician board membership
i. IRS may be relaxing this to 49% as long as physician board members are insulated from decisions about physician compensation and other conflict of interest protections are in place.

b. free emergency care

D. The “Corporate Practice of Medicine” Doctrine

a. Doctrine – practice of learned professions by profit corporations functioning through duly licensed practitioners tends to debase the profession. Fear of undue influence in the pursuit of profit. Bartron v. Codington County

i. Another view – real issue is whether individual case physicians are actually controlled in their purely professional functions by unlicensed persons in such a manner as to nullify the purpose of the licensing statute.

ii. Prohibition of corporate employment of physicians – illegal because acts of physician are attributable to corporate employer, which cannot obtain a medical license.

1. Jurisdictional exceptions:
   a. Hospital employing physician is not practicing medicine, just making treatment available.
   b. Corporate practice doctrine inapplicable to nonprofit hospitals and health associations.
   c. Not applicable to hospitals that employ physicians because other statutes allow hospitals to provide treatment to patients. Berlin v. Sarah Bush Lincoln Health Center

b. Professional Corporations (PC) – most obvious exception to the doctrine; allows practice groups entirely owned by physicians – can enjoy liability protections of corporate ownership while enjoying tax benefits of practicing as a partnership.

c. HMOs – state statutes frequently provide protection form doctrine, but federal law did not include in its preemption provision.

E. The Physician and the Hospital

a. Covenants not to compete – physicians have been successful in challenging them; but, are upheld if they are reasonable as to duration, geographic scope, and the range of activities covered, and if they are not otherwise contrary to public interest.

i. Public policy –
   1. Some courts will not allow covenants that restrict physicians whose specialty services are needed in the community.
   2. Other courts find that public interest is equally served if physicians treat patients in other areas.

b. Judicial Review of Medical Staff Decisions 1260-66

F. The Physician and the Managed Care Network – issues that arise when HMOs exclude or terminate physicians from their networks.

a. Termination without cause provision in network contract –
   i. Court found that physician-network relationship is not strictly employer-employee; also
   ii. Public has substantial interest in relationship between HMO and their preferred provider physicians.
   iii. Based on these reasons, decision to terminate must be based on covenant of good faith and fair dealing – terminated physician entitled to review of termination decision. Harper v. Healthsource New Hampshire, Inc.
b. Harper case not common – most states uphold freedom of contract in these types of disputes.
   i. One case found that patients have no right to challenge termination of their physicians.

c. Deselection – Harper case; most HMO bylaws contain some of the same due process hearing protections as do medical staff bylaws; these only apply only to physicians once they join the network.

d. Quasi-public common law theory – should courts review HMO network decisions with the same degree of care as hospital staffing decisions? Only California applies this standard.

G. Referral Fees and Fraud and Abuse Laws
a. Referral Fees – explicit or implicit incentives to generate or refer medical business; violations can result in denial of payment, inability to enforce contracts, or even criminal penalties.
   i. Kick-backs – Where defendant/diagnostic service forwarded a portion of Medicare payment for use of defendant services to referring physician, defendant guilty of Medicare fraud (kick-backs). United States v. Greber [court instruction – defendant paid physician some part of Medicaid fee, did so knowingly and willingly with the intent to induce physician to use defendant’s services for patients covered by Medicare.
   ii. Physician self-referral – where representative of physician self-referral company implied that physicians would have to make certain amount of referrals to stay in company, she violated SS act. The Hanlester Network v. Shalala – This arrangement is now ILLEGAL under the Stark Bill.
   iii. Text of referral statute – 42 USC §1395nn
      1. Prohibited referrals – physicians may not make referral to entity of furnishing of health services if the physician has a financial relationship with the entity. (An ownership or investment interest; or a compensation arrangement.)
      2. Exceptions – physician’s services, in-office ancillary services

b. Sources of law
   i. Federal - primarily civil, not criminal – main effect is to disallow payment; imposes strict liability [only matters that defined relationship exists – does not look to intent.]
      1. Medicare/Medicaid fraud and abuse statute
      2. Self-referral legislation – Stark Bill – applies to self-referral arrangements in which physicians are rewarded for sending or keeping business in institutions they own, contract with, or are employed by. [Hanlester arrangement now illegal.]
   ii. State –
      1. Statutes
      2. Medical Practice Acts

V. The American Health Insurance System and Its Reform

A. History and Sources of Health Insurance in America
a. Sources of payment:
   i. out-of-pocket – treats health care as a typical consumer good.
      1. Problems:
a. Health care regarded as a basic human need, people unable to pay must have some sort of payment mechanism to get the necessary care.

b. Price and necessity of care is unpredictable.

c. Consumers have little idea of what they are buying.

ii. individual private insurance – covers less than 10% of US population.

iii. employment-based private insurance – initiated by health care providers attempting to secure steady source of income; employers pay majority of premiums – taxable neither to employer nor employee.

1. Community rating – all subscribers pay same premium, regardless of their likelihood of developing disease or utilizing health care.

2. Experience rating – sets premium according to experience of each group in using health care (i.e. miners would pay higher premium than bank worker).

iv. government financing

1. Medicare

a. Part A: hospital insurance plan for the elderly financed largely through SS taxes from employers and employees.

b. Part B: elective provision, insures the elderly for physician’s services and is paid for by federal taxes and monthly premiums from the beneficiaries.

b. Sources of coverage:

i. uninsured

ii. individual private insurance

iii. employment-based private insurance

iv. government

c. Private Health Insurance

i. Insurance regulation – primarily by states; meant to ensure financial soundness and to impose other consumer protection measures such as fair marketing and reasonably policy terms.

ii. Risk selection techniques –

1. Experience rating

2. “Medical underwriting” – motivation to avoid high-risk subscribers

3. Exclusion of pre-existing conditions

B. Medicare and Medicaid

a. Medicaid – provides coverage to the “worthy poor” – those unable to work due to disability, or being a single parent.

i. Administration – Jointly administered by states and feds; states have great flexibility in structuring programs, so programs vary greatly by state.

ii. Eligibility:

1. AFDC recipients – young women and children,

2. SSI recipients – generally old, severely disabled.

3. States given option of covering the “medically needy” – individuals, who, except for their income, meet the other requirements for SSI or AFDC.

iii. Program design:

1. Statute set forth:

   a. mandatory features state programs must contain to qualify for fed support;

   b. program options states can elect to include; and
c. program areas for which state can get waivers of federal program requirements to adopt unique state approaches to providing and paying for health care services for Medicaid beneficiaries.

2. Coverage:
   a. Mandatory – p.1035
   b. Medicare – provides short-term medical services to elderly; employees make mandatory contributions to dedicated trust funds during their working years to cover the costs after retiring.
      i. Benefits – mostly covers acute care.
         1. Part A: finances inpatient hospital services, care in skilled-nursing facility for continued treatment or rehabilitation after hospitalization, home health care services, and hospice care for terminally ill.
         2. Part B: Supplemental coverage – pays for physician’s services and outpatient hospital services.

C. Health Insurance Coverage Disputes – claims are matters of contract interpretation.
   a. Experimental procedures – where coverage contained statement that insurer reserved the “right to change,” insurer not obligated to reclassify treatments on the basis of competing medical experts in any timely manner. Bechtold v. Physicians Health Plan of Northern Indiana

D. Provider Reimbursement Mechanisms

E. Regulation of HMOs and Other Insurance/Provider Arrangements

F. Health Policy Issue:
   f. Universal Health Coverage
   g. Rationing and Cost Containments