I. Introduction
   A. The Professional Paradigm of Medical Care: Obstacle to Decentralization—Havighurst
      a. We have a deep seated belief that medicine is not a commodity
      b. Egalitarian Ideal: Every citizen should receive the same quality of medical care
      c. Contrast with the business paradigm:
         1.) Believe that medical care should be evaluated only the basis of safety and efficacy not cost
         2.) Don’t want cost considerations to be a part of medical decision making because we do not wish to trade off patient’s needs against societal needs
         3.) Want decisions about utilization based on scientific evidence and expert opinion
   B. Health Care Past and Present—Rhodes
      1. Development of medical profession linked to advances in science—the x-ray, ether, antisepsis that allowed us to control death—don’t often focus on successes
   C. Clinical Decision Making From theory to practice
      1. now challenging basic assumption that whatever the physician does is correct.
   D. Law vs. Medicine
      1. Can be seen as a culture clash—Daniel Fox
   E. Lurking Problem: How to Ration
      1. Patient Power: Solving America’s Health Care Crisis notes that demand is virtually unlimited
      2. Making Medical Spending Decisions: The Law Ethics and Economics of Rationing Mechanisms
         a. Medical needs are not likely to reduce over time because aging and illness are a permanent part of our society
         b. Basic Questions of Rationing:
            1.) Who should decide
            2.) What should criteria b
II. The provider-patient relationship

A. Overview

1. Illness
   a. How to define
      1.) Would it benefit from medical intervention
      2.) What are we willing to pay for? What will we seek treatment for?
      a) Making Medical Spending Decisions, Mark A. Hall
         i. Notes that illness makes us vulnerable and attacks our conception of self.
         ii. notes that the process of treatment irregardless of content has healing power

2. Treatment
   a. Sometimes treatment helps even when we don't know the illness
   b. Magic or Medicine? Robert Buckman & Karl Sabbagh
      1.) Cross-Cultural similarities with interactions between healers and patients:
         a) Seek help, doctor tries to find the cause, doctor makes intervention and there is an outcome

3. Fiduciary Duty
   a. Not new duties, but a legal statute that heightens contract or tort duties
   b. Common duties
      1.) Act in best interest
      2.) Confidentiality
      3.) Loyalty/Good faith
      4.) No self-dealing
      5.) Conflict of interest
      6.) Duty to disclose

B. Duty To Treat Patients

1. common law rule: no duty to treat—both parties must agree

2. Hurley v. Eddingfield (1901)
   a. Family physician refused to come treat
   b. Held: no obligation to treat everyone who applies for services—license to practice medicine does not require physician to practice at all.
      1.) Each bout of illness requires a separate treatment relationship

3. Wilmington General Hospital v. Manlove
   a. Hospital declined to treat infant because he was under the care of another doctor.
   b. Held: Private hospital is not quasi-public and has no duty to unconditionally provide emergency room services, but if they do operate an emergency room, they may be liable for a refusal to provide care in an unmistakable emergency where the patient has relied on the fact that the hospital has an emergency room.
1.) Unmistakable evidence of emergency must be at time—experienced nurse would have seen—not case here
2.) Not holding hospital to be a “common calling” like innkeepers where cannot turn away w/o good reason or “businesses affected with a public interest” like utilities and trains
c. Doctor’s on-call for emergency rooms are held to undertake the hospital’s greater duty of care
4. Sophie’s Choice: Medical and Legal Responses to Suffering Lois Shepherd
   a. Should suffering create a right to relief?
5. No moral/Constitutional right to health care
   a. But confined individuals under state control may have right to treatment
6. EMTALA
   a. Burditt v. US Department of Health and Human Services
      1.) EMTALA requires that hospitals that execute Medicare provider agreements with the federal government treat all who present for emergency room services. Must provide an appropriate medical screening to determine if there is an emergency or active labor and stabilize or provide treatment such that no material deterioration is likely to result from transfer
      2.) Physician who transferred patient in labor with high blood pressure liable because the risks of transfer did not outweigh the benefits.
   b. Emergency situation: health in serious jeopardy, serious impairment to bodily functions, serious dysfunction of bodily organs or part.
   c. Baby K case held no “futile” exception—hospital has duty to give ventilator to anecephalic child
   d. Duty under EMTALA only arises once patient arrives at emergency room—courts have been more lenient in allowing hospitals to direct to other hospitals
   e. Need to distinguish between denials of care and negligent provisions of care—EMTALA satisfied if treated like treat other patients, may still have state tort law claim.
   f. Patients, Gov’t, and hospitals can sue under EMTALA
      1.) Remedies
         a) Fines 25-50k per violation, reimburse hospital that they dumped patient to, Medicare program
         b) Private right of action—person filing claim in court can be entitled to something too
         c) Can also go through HHS investigation, hearing, appeals to review board, then to appellate court
C. Formation, Limitation, and Termination of the Treatment Relationship
   1. formation
      a. clear most of the time—patient seeks care and provider provides
b. **Clanton v. Von Haam**  
1.) Clanton called doctor who had previously treated her for another condition, he returned call, listened and possibly said would see in morning  
2.) Held: No treatment relationship because patient interpreted phone call as a refusal of care. Had he indeed told her he would see her, and she relied on those assurances to her detriment then she might have a claim  
3.) Some courts differ and say telephone calls enough—question for jury whether advice was enough to create relationship  
c. **Reynolds v. Decatur Memorial Hospital**  
1.) Emergency room doctor called another doctor to consult.  
2.) Held: No treatment relationship between consulting doctor and patient—informal inquires from other doctors do not result in a duty of care.  
3.) Third party requests can create treatment relationship—but here there was no request for services  
4.) Some courts say duty of care to extent of involvement  
5.) Direct financial or supervisory relationship may be liability  
   a) Supervisor of medical residents can be liable, resident only liable for gross or intentional negligence  
6.) Relationship if gave care: unconscious patient/ only did lab work  
7.) Scheduling appointment generally creates relationship  
d. **General Rule: No treatment relationship when examining on behalf of third party**  
1.) Exception: affirmative advice may create relationship  
2.) Duty not to harm  
e. **Can not refuse for discriminatory reasons**  
1.) Refusals under ADA—courts may apply balancing test to determine if refusal/added requirements were reasonable  

2. Limiting the Scope of the Treatment Relationship  
a. **Tunkl v Regents of U of Ca**  
1.) Tunkl signed a release while in great pain, sedated, and unable to read that absolved the hospital of any negligence liability  
2.) Held: Release void as against public policy: 1) business is generally suitable for regulation 2) offers services of great importance, 3) matter of practical necessity for some members of the public 4) has shown a willingness to offer this service to any member of the public who meet certain standards 5) has a bargaining advantage and 6) control of the seller puts the consumer at risk.  
b. Partial waivers such as mandatory arbitration clauses may be allowed  
c. Some states have “conscientious objector” statutes protecting doctors who do not wish to participate in, refer to, or discuss abortion
3. Terminating Treatment Relationship
   a. Payton v. Weaver
      1.) Provider wished to terminate treatment relationship for dialysis of non-compliant patients
      2.) Held: General Rule that physicians may terminate only after notice and an ample opportunity for the patient to secure replacement medical care. Doctor and Clinic did not violate.
      3.) Where hospital has unique or scare medical resource necessary to preserve life, hospital is acting in the nature of a “public enterprise” and should not be allowed to arbitrarily withhold services or without reasonable cause.
      4.) May be collective duty of providers in community to share difficult patients
   b. Nonpayment can be reason for termination as long as follow steps

D. Confidentiality
   1. Duty to Maintain Confidentiality
      a. Doe v. Marselle
         1.) Doctor allowed assistant to disclose to others that patient was HIV positive. State statute said liability for willful violations of obligations to keep HIV information confidential.
         2.) Held: Willful violation does not mean actual intent to injure the patient, just that the physician acted intentionally, knowingly.
      b. Common law actions
         1.) Most states have cause of action against providers who disclose confidential information received in the course of treatment
            a) May be fraud/misrepresentation claim, malpractice, breach of fiduciary duty, or breach of specific statute
            b) Physicians may be liable for disclosures made by those under their control and direction
         2.) May also be subject to professional discipline
      c. State/federal health care providers
         1.) Patients may have constitutional right to privacy
      d. Rules of evidence
         1.) Usually protected under state rules of evidence, not included in list of privileges in federal rules of evidence
      e. Exceptions
         1.) Consent
         2.) Necessary to protect health and safety of patient or third parties
            a) May have affirmative duty to breach in such situations
      f. Medical records
         1.) Health care providers own records, patients have limited right of access under state law
         2.) IL hospitals have duty to keep medical records confidential.
            a) IL definition of willful—actual or deliberate intention to cause harm or utter indifference or conscious disregard.

2. Duty to Breach Confidentiality
a. Some states like Florida, require that providers report elder/disabled abuse
b. Some require to report evidence of crime—gunshot or knife wounds
c. May have to report information about contagious diseases
d. SC struck SC practice of testing pregnant women for cocaine and notifying police.
e. **Bradshaw v. Daniel**
   1.) Patient died of Rocky Mountain spotted fever and doctor did not advise wife of risk.
   2.) Held: Duty to warn where there is a foreseeable risk of harm to an identifiable third party.
   3.) Still have to prove other elements of negligence
f. Because talking about nonfeasance, not misfeasance, need a special relationship
g. Scope of duty defined by the nature of the risk and the providers ability to reduce the risk
   1.) Contagious diseases
   2.) Genetic conditions
   3.) Mental illness—duty to protect others—Tarasoff
      a) Some courts limited to if had ability to control
   4.) Driving impairments
h. Debate over whether actual knowledge is required—Tarasoff knew or should have known standard
i. Duty may be discharged just by warning patient

E. Informed Consent

1. Goals Aspirations, Policies
   a. Informed consent challenges historical notions of physician’s supremacy and authority
   b. **Patient Centered Medicine: A Professional Evolution** Christine Laine & Frank Davidoff
      1.) Patients now expect to know diagnosis, treatment options, prognosis
   c. **Rethinking Informed Consent** Peter Schuck
      1.) Idealists view informed consent from the point of view of the patient. Realists question whether this is what most patients really what and whether it holds up to cost-benefit analysis.
      2.) “Informed Consent Gap” between law in books and law in action
d. *gap between disclosure and retention*
e. Carl Schneider has suggested that patients really want to be informed without the authority to make the final decision
f. Spectrum of Standards
   1.) Professional Malpractice—reasonable physician standard
      a) Majority standard
   2.) Reasonable patient or material risks standard—must disclose risks that reasonable patient would consider material
      a) Growing minority
3.) Small minority require disclosure of risks that particular patient would have wanted
4.) Small minority use fiduciary duty standards

2. The Professional Standard
   a. Culbertson v. Mernitz
      1.) Culbertson was not informed of risk of cervix adhering.
      2.) Held: Expert testimony is required to show the standard for informed consent—doctor should only have to act as reasonable physician would.
   b. Traditionally limited to doctors—not extended to hospitals
      1.) Even if hospital is one that gets patient’s signatures
   c. Prima Facie Case
      1.) Medical procedure carried risk not disclosed
      2.) Reasonably prudent physician would have disclosed the risk
         a) Must disclose alternatives if reasonably prudent physician would have done so
      3.) Undisclosed risk materialized
      4.) Failure to disclose caused injury
         a) Most jurisdictions have to show that reasonable patient would not have undergone treatment
   d. Don’t usually use battery theory—many insurance policies don’t cover and it is difficult to prove when medical treatment is noninvasive. Usually used where:
      1.) No consent to any treatment
      2.) Completely different procedure than one consented to
      3.) Wrong area of the body
      4.) Different unconsemted provider performs surgery
      5.) All informed consent in PA grounded in battery
   e. Rizzo v. Schiller
      1.) Ms. Rizzo signed a consent form, but her expert witness also testified that reasonable doctor would inform of risks of using forceps.
      2.) Held: Has a prima facie case, duty of informed consent extends to more than general consent form.
      3.) General consent forms usually not enough, some states like Ohio have made statutory presumption in favor of consent forms that set out the nature and purpose of the procedure, risks and who will perform it.
   f. No duty of informed consent
      1.) Patient is incompetent and immediate treatment is necessary
      2.) Risk of disclosure presents a serious threat to psychological well-being
   g. Informed consent important when physician is in “respectable minority, to try out research or new procedure or to show contributory negligence/assumption of the risk

3. Material Risk Standard
a. **Canterbury v. Spence**
   1.) Doctor did not disclose risks of back surgery to son or mother.
   2.) Held: Physicians have an obligation to make reasonable disclosure of risks and choices of alternative therapies. Duty is measured by what is reasonable under the circumstance—the material risks a reasonable person would have wanted to know.
   a) Weigh incidence and degree of risk, relation of risk to proposed benefit
   3.) Not necessary to disclose:
   a) Risks inherent in any operation that average person is aware of
   b) Information not material to the decision
   c) Information patient already knows
   d) Emergencies
   e) Therapeutic privilege—would pose psychological damage
   4.) Considered from point of view of reasonable person in plaintiff’s situation

4. Fiduciary Principles and Conflicts of Interest
   a. **Autonomy and Privacy: Protecting Patients from their Physicians**
      Mary Anne Bobinski
      1.) Fiduciary duty as a way to expand the duty to disclose
   b. **Moore v. Regents of U of Ca**
      1.) Researchers did not inform patient that they intended to use his samples to form a patented cell line.
      2.) Held: Patient has a cause of action for breach of disclosure obligations (either breach of informed consent or breach of fiduciary duty), but no action for conversion.
   a) Research creates conflicting loyalties and must disclose all personal interests which may be material to the patient’s decision
   3.) Must also disclose any material economic interest (referring organization, funding, source of research).
   c. **Shea v. Esenten**
      1.) Doctor did not tell patient that he received a bonus under HMO incentive programs for not referring to specialists and was penalized for too many referrals.
      2.) Held: Fiduciary duty of health plan under ERISA extends to duty to disclose financial considerations that might affect care
      3.) Compare Pegram v. Herdich—SC court said that can’t bring an ERISA claim against HMO addressing individual treatment decisions—but won on state law malpractice claim against doctor.

   d. **Pharmaceutical Marketing**
      1.) Kickbacks and direct financial incentives illegal, but usually do not have to disclose “perks.”
III. Adverse Medical Outcomes

A. Medical Error

1. Nature and Extent of Error

   a. Variations in Physician Practice: The Role of Uncertainty
      David Eddy
      1.) Uncertainty over what is a disease—symptoms but no obvious
          illness, disease but no symptoms except for increased risk—
          coupled with individual variation among doctors in selecting
          procedures means that we can only talk about probabilities of
          outcomes. Any procedure has multiple possible outcomes.

   b. Making Medical Errors into Medical Treasures
      David Blumenthal
      1.) Public used to grant physician’s authority based on the idea that
          error-free medicine was possible

   c. Error in Medicine
      Lucian L. Leape
      1.) Large percentage of patients 4-20% suffer iatrogenic injury—
          one caused by treatment
      2.) Physicians socialized to strive for error-free practice and to
          assume that error is always caused by negligence—errors are
          thus rarely admitted
      3.) Types of error
          a) Slips—monitoring errors—loss of attention causes
             unintended error
          b) Mistakes—
             i. rule-based error
             ii. knowledge-based error
             iii. Elliot Freidson in Doctoring Together makes
                 distinction between normal mistakes and “deviant”
                 mistakes
             iv. Jost: Distinction between medical errors and medical
                 failures

   d. A Complex Sorrow: Reflections on Cancer and an Abbreviated Life
      Marianne Paget
      1.) Author was diagnosed with incurable cancer as a result of
          series of error notes that while mistakes are common, most are
          not negligent and thus not compensated—notes that what is
          really important is getting someone to admit mistake.
      2.) Doctors suffer similar mixed feelings—Eliot Perleman excerpt—
          regret over bad outcome, medical malpractice suit as affront to
          integrity and reputation.

   e. 180,000 deaths a year from medical error
   f. more doctors being sued, but doctors also usually win

2. Approaches to Improving the Quality of Care

   a. The Necessary and Proper Role of Regulation To Assure the
      Quality of Health Care
      Timothy Stolzfus Jost
      1.) Debate over how to handle error
a) Professional ethics and socialization are enough
b) Market forces are enough
  i. Depend on ability of consumers to make choices
c) Self-regulation: socialization, informal review, accreditation, certification and hospital staff privileges
d) Medical malpractice
e) (could also use no-fault system)

2.) How to evaluate error
   a) structural evaluation—focuses on capacity to deliver care
   b) process evaluation—focuses on how the care is delivered
   c) outcome analysis—looks at the result of care

b. Oversight of the Quality of Medical Care: Regulation Management or the Market? Timothy Jost
   1.) Total Quality Management (TQM) part of continuous quality improvement (CQI)—assumes that professionals only need better information and support to do better job
   2.) How to improve quality: could use information, professionalism, sanctions, incentives
   3.) Most problematic is idea of comparison shopping for health care—how will consumers use information

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   4.) new government efforts to monitor through “score cards”

B. Licensure of Medical Professionals
   1. The Abuse of Professional Licensing Walter Gellhorn
      a. Public Safety is really a pretext for protecting professionals from outside competition
   2. Licensure allows the profession to control entry into the market place—may argue quality control, but also regulates the supply of physicians
   3. Licensure—absolute bar where under a system of accreditation or credentialing a patient would be free to seek care from uncertified or unaccredited provider.
   4. State v. Miller
      a. Miller treated patients in his home by “radionics” and “function generators” and vitamins
      b. Held: Properly convicted of practicing medicine without a license under Iowa law because he met criteria of “publicly professing to assume duties incident to the practice of medicine” by leading patients to believe he could diagnosis and treat ailments and “prescribed or furnished medicine.”
   1.) Typical of statutes that prohibit holding oneself out as being able to diagnosis, treat, prescribe, for any human disease, pain, injury, deformity, physical or mental condition
   2.) Other cases have attacked audio weight loss tapes and won

5. no constitutional right to provide care or to choose non-traditional care—upheld under rational basis test
6. some states have exception for religious practitioners
7. midwifery commonly upheld as practicing medicine without license
8. interprofessional disputes common
9. some states have tried to limit physician’s ability to delegate to others
10. **Regulatory System in Shambles; Negligent Doctors Stay on the Job**
    Boston Globe
    a. Problem that even doctors frequently accused of and convicted of malpractice do not loose license

C. Medical Malpractice
   1. Physician Liability
      a. Prima Facie Case
         1.) Applicable standard of care
         2.) Breach of standard of care
         3.) Injury
         4.) Proximate causation
         5.) To get punitive damages need willful, wanton, reckless behavior or reckless omission—relatively rare
            a) Most common: Failure to aggressively treat a seriously ill patient, failure to admit mistake, altered records
      b. the custom based standard
         1.) McCourt v. Abernathy
            a) Patient died of sepsis because she was not put on antibiotic soon enough
            b) Held: Standard is what an ordinary careful and prudent physician would have done under the same or similar circumstances
         2.) Locke v. Pachtman
            a) Needle broke during hernia repair.
            b) Held: Plaintiff bears the burden of establishing the standard of care through expert testimony. Plaintiff's expert failed to establish what the relevant standard was because she never said exactly what a reasonably prudent doctor would have done.
            c) Some courts would agree with dissent and allow alternative proof where as here the treating physician has admitted a departure from the standard of care
         3.) **Universal Health Care and the Continued Reliance of Custom in Determining Medical Malpractice** James Henderson & John A. Siliciano
            a) Many new choices plus patient as ultimate decisionmaker means it is difficult for profession to reach a consensus
        4.) Custom based standard is more protective of doctors than other tort defendants
        5.) Some argue that the custom based standard separates malpractice from the rest of ordinary negligence as a separate branch of tort law, others like CA Supreme Court see custom as additional circumstances that determine what prudent person would have done under the circumstances.
c. variations on the custom based standard

1.) Jones v. Chidester
   a) injury from tourniquet in surgery
   b) Held: The defense of two schools of thought is a complete
defense and requires that a considerable number of
respected doctors use.
   c) Some jurisdictions require considerable number, and some
require that respected physicians use it
   d) Most courts also have standard of reasonable
experimentation where the innovation is for therapeutic
reasons not just research curiosity
      i. May also be protected by informed consent, even
where a comparison with the standard therapy was not
offered as long as knew that this was an experiment, and
the risks and benefits of the experimental therapy
      ii. Doctors who practice unorthodox or “unscientific”
medicine may also be protected by informed consent

2.) Chapel v. Allison
   a) Injured in rural Montana, local doctor set leg.
   b) Held: Standard is that of a similarly qualified general
practitioner in the same or a similar community in the US
under the same or similar circumstances.
   c) Older rule: same locality rule—restricted standard of care to
that of the community where the doctor resided
      i. Exception where testimony is that local standard is
national practice
   d) Some jurisdictions: doctor, with similar qualifications, in
same or similar community within that state
   e) Move is towards more national standard of care

d. The ordinary negligence standard

1.) Helling v. Carey (WA)
   a) Took ten years for defendant’s to diagnosis plaintiff’s
glaucoma
   b) Held: Even though complied with standard of care, still liable
if reasonable prudence requires—law can say that even if
profession has not adopted, some precautions are so
imperative that even universal disregard does not excuse
omission.

2.) Medical Uncertainty Diagnostic Testing and Legal Liability Eric
Fortess & Marshall B. Kapp
   a) Is defensive medicine really a problem or is it physicians
desire to know as much as possible—Helling as an anomaly

3.) One Hundred Years of Harmful Error: The Historical
Jurisprudence of medical malpractice Theodore Silver
   a) Anomaly that physicians can determine their own legal
standard
b) Better to base negligence on Learned Hand’s formula:
   i. B<PL
   ii. B= Burden, P= Probability, and L= Injury
4.) Defensive medicine
   a) Doctors ignore risks of nonbeneficial defensive medicine because risks unlikely to result in large damages
   b) Negative defensive medicine discourages certain procedures or specialties

e. The role of experts in litigation
   1.) need experts to prove standard of care and breach, and proximate causation. May not need an expert in all cases to prove injury
   2.) Thompson v. Carter
      a) Trial court did not allow pharmacologist to testify as to liability and causation with regards to drug
      b) Held: If the expert witness has the necessary medical knowledge, it is not necessary that he possess a medical degree to establish the standard of care.
      c) Spilt in courts over whether nonphysicians can establish the standard of care
   3.) Broders v. Heissey (in class discussion)
      a) Even though ER doctors made the error, plaintiff should have put on neurologists like defense did. Not every expert qualified to testify on every issue.
   4.) Trower v. Jones
      a) Expert in misdiagnosis case worked for a for-profit group that reviewed medical records for a fee.
      b) Held: Acceptable cross-examination to probe possible bias, partisanship or financial interest
      c) Majority of jurisdiction allows impeachment of “hired guns”
   5.) Geographic dimension
      a) Not necessary for expert, even under strict locality standard, to actually reside in area if he has knowledge of local contacts
   6.) Number of states have statutory reforms on experts.
      a) Examples:
         i. Requiring to live in or near state
         ii. Be in active practice in recent years
         iii. To practice in same or overlapping specialty or to have performed the same type of procedure in recent years
         iv. Licensed in same professional categories
   7.) Evidence
      a) Stang-Starr v. Byington
i. Plaintiff injured by doctor’s failure to diagnosis wanted to question her experts about the texts and treaties they relied on.

ii. Held: Cannot use witness as a conduit for hearsay—can not use witness to recite opinion of others

iii. Experts can rely on sources other than admissible evidence, but just because relied on does not make it admissible

b) Emerging approach in Federal Rules of Evidence § 803(18) is to allow expert testimony to recite learned treatises, guidelines or other authoritative sources

c) Unique status of package inserts—some courts say prima facie evidence of standard of care, may be rebutted by showing that physicians commonly depart

d) Other practice guidelines, harder to introduce into evidence

i. Some states like Maine allow defendant to introduce as affirmative defense, but plaintiff may not admit

e) Controversy over whether “report cards” should be admissible

2. The importance of proving causation


1.) Died of lung cancer after doctor treated only for coughing—but probably would have died anyway

2.) Held: Restatement of Torts allows recovery based on theory that one increases the risk of harm—reduction of even small chance can be actionable.

a) Some jurisdictions can recover for “lost chance” others need more likely than not that would have recovered—like concurrence argues—“might” is not enough. Few courts require “reasonable medical certainty”

b. Lost future chance generally not recoverable, although can usually recover medical monitoring costs

1.) Exception—present actual injury that may get worse

c. Errors in diagnosis, most likely to have causation issues, followed by errors in choice of treatment and errors in surgery being the least likely to present causation issues

d. Traditional Approach to Causation

1.) But for test

a) “more likely than not” 51%

b) “reasonable medical certainty”

c) some cases like Nebraska look like they want something closer to reasonable doubt standard

3. Statutory reforms

a. Fein v. Permanente Medical Group

1.) State law limits noneconomic damages in medical malpractice suits
2.) Held: No violation of due process because no property right, no vested interest in particular measure of damages. No equal protection claim.
3.) Other states have invalidated statutes that limited economic damages

b. Crushed by my own Reform Frank Cornelius
   1.) Lobbyist who got a $500,000 cap on damage awards was victim of medical errors that confined him to wheelchair, $5 million in expenses says damage caps are arbitrary and give special protection to medical industry.

   1.) “Crisis” in malpractice really one of affordability and availability of insurance and a sense of injustice in tort law
   2.) Main complaints: too many lawsuits, too much damages, poor jury decisions on fault
   3.) Reforms thus address insurance, law (tort reforms) and medical reforms
      a) Insurance reforms:
         i. claims made coverage (pay for claims brought in policy year instead of traditional policy of covering claims arising from policy year)
         ii. joint underwriting associations—state overseen insurance pool that guarantees solvency
      b) Tort Reforms:
         i. Reforms to reduce number of lawsuits: Attorney fee controls, Arbitration, Pretrial screenings, Certificates of merit, Statutes of limitations
            (a) Attorney fee limitations—contingencies already within system: low recovery rate, expert fees, settlement
            (b) Screening panels usually composed of doctors and lawyers—usually nonbonding but in a few states have the power to dismiss
            (c) MO need “affidavit of merit” from doctor saying that case has merit
         ii. Reforms addressing size of recoveries: restricting ability to list amount sought in initial complaint, damages caps: noneconomic or on total awards, allow or mandate structured awards that make periodic payments, collateral source offset
         iii. Reforms to address likelihood of winning: limitations on doctrine of informed consent, shifting burdens, reassertion of locality rule, restricting res ipsa loquitor
         iv. No fault schemes: VA and FL use for birth injuries, National Childhood Vaccination Act
Also move to allow private contracting—“opt out” and exclusive enterprise liability—shifting focus from physicians to enterprises where they practice (already exists by virtue of private agreement in many HMO’s and private hospitals)

4. Hospital liability
   a. Schloendorf v. Society of New York Hospital (1914)
      1.) Patient suing non-profit hospital for performing operation she did not consent to
      2.) Not liable for negligence on several theories: Implied waiver of one accepting charity, no master-servant relationship with physicians. But can recover on theory of trespass even though charity hospital but still barred by fact that wrong committed by physicians who were not employees.
      3.) Attitude towards charitable immunity changed as hospitals became more like businesses
      4.) Most states have abrogated governmental immunity to some degree, although still common for psychiatric hospitals
      5.) No vicarious liability even for nurses shifted to series of decisions distinguishing between administrative errors and errors of medical judgment
   b. Adamski v. Tacoma General Hospital
      1.) Sued emergency room doctor and hospital for negligence under a theory that the doctor was the hospital’s agent
      2.) Held: Respondent Superior applies if the doctor and hospital have a “significant relationship” determined by factors:
         a) Who bills
         b) Whether the doctors receive other compensation
         c) Whether the doctors agreed not to have a private practice
         d) Who provided insurance
         e) Who ran the department
         f) Whose rules governed
         g) Length of K
         h) Who owned equipment
         i) Whether patient had choice
         j) Whether service was “inherent function of hospital”
         k) Do not need actual control as long as negligence within course and scope of employment
      3.) Even where not actual agent, hospital could still be liable under a theory of ostensible agency where the patient had reasonable belief that the doctor was acting as the hospital’s agent even where there is no affirmative misrepresentation
         a) Most courts—emergency room physicians ostensible agents regardless of arrangement
         b) Most courts do not require strict reliance—do not require patient to show that they would have declined treatment
4.) May also be liable under a theory of nondelegable duty or enterprise liability
   a) Liable for negligence within the scope of the hospital enterprise
   b) Argument is that public policy requires that hospital not delegate certain functions like emergency rooms to independent contractors
5.) CA Brown Formula: respondent superior applies where a patient sought treatment primarily from the hospital and the doctor was paid by the hospital on a salary basis.
c. “captain of the ship” doctrine—physicians may be liable for subordinate doctors and nurses, if independent can be found to have “borrowed” the hospital’s employees. Many courts find that the doctor and hospital share the employee and are both liable.
d. Other theories of liability for hospital: Direct Liability
   1.) Hospital’s negligence
   2.) Negligent selection
   3.) Negligent supervision
   4.) Negligence in care
   5.) Enterprise liability
5. Medical malpractice in managed care
   a. Wickline v. State
      1.) Sued California Medicaid program because it cost containment measures led doctors to discharge her too early
      2.) Held: Doctors bear primary responsibility for patient care and deciding whether discharge is appropriate and they should have filed another request for extension.
      3.) Dicta: Third-party payers can be liable when medically inappropriate decisions result from defects in design or implementation or cost containment mechanisms—if appeals were arbitrarily ignored. But can not be liable where physician complies without protest.
b. What is managed care?
   1.) Broad term referring to variety of arrangements that may have one or more of the following:
      a) Restrict patient choice
      b) Use utilization review/authorization to effect treatment decisions
         i. Other possible methods of cost and quality control: quality assurance programs, dispute management programs
      c) Create financial incentives through capitation payments and risk sharing pools
      d) HMOs do all three.
         i. Independent Practice Association—large contractual network of providers
ii. Agency or staff model HMO—doctors work exclusively for HMO usually out of HMO clinic

iii. Federally qualified HMO's must have ongoing quality assurance program

iv. May be accredited—NCQA most common

c. Like hospitals, plaintiffs may challenge negligent selection/supervision
   1.) But some states have “any willing provider laws” that networks have to accept any willing provider
   2.) Open question as to whether ERISA preempts

d. Might challenge on contract grounds: breach of K, fraud, misrepresentation, false advertising, bad faith

e. Other Forms of direct Tort liability: negligent utilization review, negligent incentivezation, informed consent issues

f. In a few jurisdictions HMOs are immune, but Texas and several other states allow suit for negligent utilization review decisions.
   1.) No ERISA preemption if only addressing negligent treatment decisions and not coverage decisions
   2.) Some seek to avoid ERISA preemption by bringing suit under RICO but need intent and conspiracy to defraud
   3.) ERISA prevents arbitrary and capricious determinations:
      a) Jett v. Blue Cross—test is whether there was a reasonable basis for decision based on facts known at that time
      b) Brown v. Blue Cross—where conflict of interest, fiduciary must show that discretion not tainted by self-interest

g. Financial incentives: Emerging principle that if underlying treatment is negligent, financial incentive can be found to be contributing factor, but that incentive arrangement by itself is not independently actionable
   1.) Bush v. Drake—plan might be liable for encouraging withholding necessary treatment
   2.) Shea v. Esenten—liable for failure to disclose incentive arrangement but 5th Cir. disagrees and says do not have to disclose

h. Bad Faith Denials of Care
   1.) Goodrich v. Atena
      a) Cancer patient died after being denied treatments—over course of 4 years recovered $120 million on theory of bad faith—most significant factor was length of time took insurance company to respond to requests.
   2.) Fox v. Healthnet
      a) Breast cancer patient denied bone marrow transplant—physician changed mind after discussion with plan directors.
   3.) Warne v. Linclon National Administrative Services—promotional materials must match certificate of exclusions
   4.) Hughes v. Blue Cross of Northern Ca.
a) Bad faith denial of care when did not conduct reasonable evaluation, give treating physician opportunity to provide additional information and did not balance the individual’s interests against the plan’s interests. But CA Supreme Court said preempted by ERISA

i. Apparent and Implied Agency
1.) Petrovich v. Share Health Plan of IL
   a) HMO handbook referred to “your share physician.” “share physicians” “our staff.”
   b) Held: HMOs may be vicariously liable under the doctrines of apparent and implied authority for negligence of physicians, even if they are independent contractors
2.) Nealy v. US Healthcare—negligence action precluded by ERISA but Pacificare v Burrage held that vicarious liability claim was not preempted
3.) General Rule: Even if no ERISA preemption no vicarious liability for independent contractor
   a) Emerging Exception: When plan requires treatment by designated physician

D. Regulation of Drugs and Medical Devices
1. United States v. Rutherford
   a. Terminally Ill Cancer patients wanted access to Laetrile a drug not approved as “safe and effective” by the FDA
   b. Held: No exception for terminally ill, FDA protects the terminally ill who are also at risk for fraud and difficult to determine when really terminal
2. no recognized constitutional right to pharmaceutical choice
3. FDA requires package inserts warning labels that end up having considerable influence on standard of care
4. Dietary supplements outside FDA as long as they do not make therapeutic claims, but if go to far and become food—food and food additives also regulated by FDA
   a. Dietary Supplement Act of 1994 drew some lines
      1.) Must be intended to supplement: Vitamin, mineral, herb, botanical, amino acid
      2.) Can make “structure and function” claims as long as do not claim to treat
      3.) Can still be sued for product liability
5. off-label use
   a. almost ½ of all cancer treatments off-label uses
   b. approved use is usually combination specific—off-label use may be new combinations
   c. off-label use not necessarily violation of standard of care
6. Most courts unwilling to hold manufacturers strictly liable
IV. The Business of Health Care

A. ERISA Preemption

1. ERISA regulates “employee benefit plans”
   a. ERISA § 514(a) provides for broad preemption “supercedes any and all state laws insofar as they may now or hereafter relate to any employee benefit plan”
      1.) But the savings clause of § 514 (b)(2)(A) allows state laws which regulate insurance, banking, or securities.
      2.) But the deemer clause of § 514 (b)(2)(B) says that self-insured employers are not insurance companies.

2. American Medical Security v. Bartlett
   a. State of Maryland requires that health insurance provides 28 specified benefits. Employers tried to get around by self-insuring and purchasing stop-loss protection. Maryland then required plans to absorb the first $10,000 of benefits paid out to each beneficiary.
   b. Held: ERISA forbids regulating self-employed insurers even if fall within savings clause. Savings clause applies if regulates “the business of insurance.” Metropolitan Life Factors: 1) allocates risk, 2) addresses practice integral to insurer/insured relationship, and 3) limited to entities within insurance industry.
   c. ERISA does allow states to regulate the solvency of those who sell stop-loss coverage

3. ERISA Preemption impacts:
   a. Malpractice actions against HMO’s
   b. Contract claims for denial of payment under health insurance
   c. State attempts to require employers to offer health insurance

4. “indirect cost or effect” on ERISA plans not preempted under New York State Conference of Blue Cross/Blue Shield v. Travelers (okay to make hospitals collect surcharges from patients covered by commercial insurance).
   a. Likewise, indirect effect on price by generally applicable tax not preempted

   b. McGann’s employer changed their plan to limit coverage for AIDS after learning McGann had AIDS.
   c. Held: § 510 only applies when the employer acts with discriminatory intent towards a specific employee not when they change the plan.
      1.) Discrimination only illegal if it is motivated by desire to retaliate or to deprive of existing benefit to which he may become entitled (no entitlement to certain level of HC
      2.) Desire to save $ not illegal.
   d. Shows the fundamental tension between ERISA’s reluctance to impose a minimum level of benefits, while still preventing individual discrimination.
6. Pilot Life Insurance Co. v. Dedueaux
   a. ERISA limits plan participant to recover benefits due under plan, enforce rights under plan, or clarify rights to future benefits—no bad faith action

7. Pegram v. Herdrich
   a. Brought action against insurer alleging malpractice and fraud and breach of fiduciary duty under ERISA
   b. Held: Mixed eligibility and treatment decisions made by HMO acting through physicians were not fiduciary acts.
      1.) Point of any HMO is to ration care—hard for courts to draw a distinction between good and bad HMO’s
      2.) Essential question is whether person was performing a fiduciary function at the time of the action in complaint—fiduciary is someone acting as manager, administrator, or adviser to plan
      3.) Court is implicitly leaving garden variety medical malpractice claims to states

B. Basic State and Federal Regulation of Health Care Facilities
   1. Licensure and Accreditation
      a. Patient Power: Solving America’s Health Care Crisis John C. Goodman & Gerald L. Musgrave
         1.) Show how one hospital must answer to 37 governmental bodies, 7 nongovernmental bodies, file about one report per 4 beds
      b. Licensure: Government process that gives facility right to operate
      c. Accreditation: certificate of quality from private organization
         1.) JCAHO—regulates every US hospital
         2.) Does accreditation raise anti-trust implications?
         3.) Move now to more competing accreditation organizations
      d. Certification: voluntary process to meet qualifications for Medicare/Medicaid programs
      e. Many have same or similar standards.
      f. Estate of Smith v. Heckler
         1.) Alleges that reviews for continuing participation in Medicaid program focus on survey questions, few of which are related to patient care.
         2.) Held: Secretary has a duty under act to provide high quality medical care and this means that regulations promulgated must allow Sec. To stay informed on a continuing basis as to whether facilities meet Medicaid requirements.
         3.) Continuing problem of how to measure quality—through structure (like Smith) or outcomes.
      g. Cospito v. Heckler
         1.) Psychiatric Hospital lost accreditation, then lost federal funding (decertified). Patients allege lack of due process because they lost Medicare, Medicaid and SSI monies.
2.) Held: Even if protected property interest, deprivation was only indirectly caused by government. Not improper delegation for secretary to make JCAHO standards the standard for certification because the Sec. Does not have to accept the JCAH accreditation.

h. Common problems:
1.) Does license cover satellite facilities
2.) Can specialty clinic be treated as doctor's office (no license required)?
3.) Does license cover buyer or lessee or management company

i. How to Challenge Adverse decisions
1.) Usually can’t challenge private accreditation constitutionally
2.) Statutory scheme usually specifies how to challenge

2. Other regulations
a. OHSA affects Hospitals by protecting hospital workers from hazardous materials and infectious diseases
b. EPA regulates hazardous waste

3. Certificate of need Regulations
a. Some states require that hospitals get certificate of need before building
b. Statewide Health Coordinating Council v. Humana
   1.) Hospital applied for certificate of need and other hospital opposed.
   2.) Held: State agency not authorized to grant certificate of need inconsistent with state health plan
   3.) Rigidly applying quantitative bed criteria—some states consider qualitative measures too
   c. Have not had hoped for effect on health costs
   d. Need for large expensive technical devices like CAT scan largely subjective

C. Nonprofits and Tax Exempt Statutes
1. Queen of Angels v. Younger
   a. Franciscan Sisters leased hospital to private company and wishes to operate clinics instead.
   b. Held: Charitable trust intended to operate hospital under articles of incorporation—can not abandon principle purpose—bound by articles of incorporation.
      1.) Doctrine of Ultra Vires—cannot deviate from charitable purpose
         a) Less strict bylaws, courts generally allow modification of corporate purpose as long as same charitable aims
      2.) Services of sisters considered donations—claim for payment not valid
      3.) Doctrine of Cy Pres: allows transfer to new corporation that “as near as possible” has same general charitable purpose—usually fairly broad
   c. Charities may also be limited by strings on gifts
d. In some cases, Catholic law may supplement secular law.

e. Board members required to act as fiduciaries and use sound business judgment.

1) Also risk of conflict of interests violating duty of loyalty.

2. **Columbia/HCA and the Resurgence of the For-Profit Hospital Business**
   
   Robert Kuttner


   b. Big for profits end up forcing nonprofits to emulate.

3. Some conversions, particularly Blue Cross/Blue Shield end up having to pay state back or settle with state.

4. **Hospital Reorganizations and Integrated Delivery Systems**

   a. Often have parent holding company, hospital subsidiary and additional subsidiaries from which components of health system are operated.

   b. Integrated delivery systems.

   1) Holding companies and other complex corporate structures can get charitable tax exemption under special doctrines of “integral part test” and “shared service organization.”

   2) Vertically integrated networks—network parent can get exemption, not necessarily component members.

      a) IRS says no more than 20% of board membership can be physicians.

D. **The “Corporate Practice of Medicine” Doctrine**

1. **Doctors, Patients and Health Insurance: The Organization and Financing of Medical Care**

   a. Ambiguous relationship with hospital—usually no administrative or financial responsibility, yet has a lot of power.

   b. Most doctors do not want to be employees.

2. **Barton v. Codington County (1942)**

   a. Clinic was operated by corporation of doctors and other employees.

   b. Held: Unlawful for corporation to practice medicine—protects stature of profession and ensures that control of medicine is in hands of doctors. Do not want trading in professional services to make profit.

   c. Argued that corporations can not meet the moral character requirements.

3. **Right of Corporation to Practice Medicine Yale L.J. (1938)**

   a. Argues that statutes preventing the practice of medicine without a license are adequate protection, states could regulate to ensure standard of ethics.


   a. Health Center hired doctor to 5 year contract.

   b. Held: Not a violation of corporate practice of medicine doctrines because other statutes authorize hospitals to provide medical treatment to patients.
c. Exceptions in some states: some say hospital that only employs physicians is not practicing medicine just making treatment available, others say not applicable to non-profits
d. Other states make exemptions clear in licensing statutes like those that allow Physicians to form Professional Corporations (get liability protection of corporation and tax benefits of partnerships) and Professional Limited Liability Corporations (PLLC’s) (limit liability like corporation, avoid entity-level tax like partnerships)
5. Doctrine underlies why doctors and hospitals must be paid separately (Medicare A & B, Blue Cross & Blue Shield)
6. Basis for rule
   a. Medical Practice Act
   b. Common law public policy
7. FTC enjoined AMA from enforcing ethical prohibitions based on corporate practice doctrine
8. Federal HMO act exempts HMOs
E. The Physician and the Hospital
1. Hospital and Medical Staff Bylaws
   a. Hospital has three lines of authority
      1.) Medical staff
         a) Self-governing with separate bylaws
         b) Some hospitals try to circumvent with exclusive contracting
         c) May cases hold that bylaws constitute contract and that hospital can not amend or circumvent unilaterally
      2.) Management
      3.) Board of directors
2. economic credentialing—issue over whether hospitals can consider economic factors in choosing physicians
   a. Some jurisdictions require that economic based exclusions be pursued through bylaws
3. covenants not to compete—must be reasonable in scope
   a. some courts say violates public policy to restrain needed specialties
4. Labor Laws
   a. Professionals can unionize as long as not management
      1.) Nurse managers, peer review committee heads, department heads excluded
   b. Congress has limited the number of bargaining units permissible in a single institution—NLRB rule limits to 8 in a single hospital
5. Excluded Physicians
   a. Greisman v. Newcomb Hospital
      1.) Doctor wanted staff privileges at hospital. Hospital Bylaws did not admit DO’s.
      2.) Held: Hospital is quasi-public institution and public policy mandates that applications be evaluated on individual merits.
         a) Court notes that bylaws different than discretionary judgments
3.) Fairness in griesman distinct from due process
   a) Fairness usually held to require notice, opportunity to present case, and right to cross-examine
   b) Health Care Quality Improvement Act allows representation by counsel and disqualifies from panel anyone in direct economic competition
4.) Some jurisdictions only apply quasi-public theory where monopoly
5.) Other invalid criteria: being member of local medical society; having a recommendation
6.) Different outcome if had based decision on quality of care

b. Nanavati v. Burdette Tomlin Memorial Hospital
   1.) Staff privileges were revoked over dispute over who should read ECG’s.
   2.) Held: Appropriate standard of review of decision of physician is whether the result is supported by sufficient reliable evidence, even if hearsay to justify the result. Mere fact that disagreeable not good cause and should not be able to use as pretext.
      a) Need concrete evidence of specific instances of misbehavior
   c. Other causes of action for excluded physician: antitrust, common law unfair competition, defamation, civil conspiracy, tortuous interference with contract, state statutory claims, constitutional or civil rights claims

F. The Physician and the Managed Care Network
   a. Healthsource terminated doctor because he reported concerns about the accuracy of patient records
   b. Held: Public policy requires that decisions to terminate must meet standards of good faith and fair dealing. This requires review of decision
   c. Other states different outcomes. Only CA has applied quasi-public, common law fairness theories to HMOs.
   d. Other employees can also bring wrongful discharge claims as well
2. minority physicians often hard hit by “deselection”
3. Despite problem of “deselection” it is often physicians themselves who argue for “no-clause provisions”
4. Many states have statutes that protect doctors who are “contentious objectors” to certain procedures
5. some doctors also bring claim of tortuous interference with relationship with patients

G. Referral Fee and Fraud and Abuse Laws
1. United States v. Greber
   a. Lab paid physicians who made referrals “interpretation fees” which raised the fixed percentage paid to each doctor to more than allowed by Medicare.
b. Held: Payments can be the basis of Medicare fraud—even if physician was acting as a consultant—if the purpose of the fee was to induce ordering of services from their lab.

2. Social Security Act 1128 (b)(2) provides: “whoever knowingly and willfully offers or pays any remuneration directly or indirectly, overtly or covertly to induce such person to purchase, lease, order, arrange for any service or item under which payment may be made for Medicare or Medicaid

3. Hansletter Network v. Shalala
   a. Physician investors formed joint venture to get $ from lab tests.
   b. Held: Physician self-referral joint ventures are acceptable even if referrals are linked to return as long as no inducement. VP’s actions were knowing and willful in telling investors return was guaranteed but employer is not vicariously liable because it did not know of her actions.
   c. Narrow construction of willfully and knowingly as knowing that law prohibits and specifically structured transaction to violate law makes prosecution difficult
      1.) 8th Cir. willful= know doing something wrongful or unjustified, but don’t need specific knowledge

4. Limitations on Certain Physicians Referrals 42 USC § 1395 (Stark bill)
   a. Physicians can not refer to organizations that they or immediate family member have financial stake in
   b. Exceptions for group practices, in-office services, or where physician owns stock at terms commonly available
   c. Hospitals must buy-out physician services with one-time payment—can’t make installment payments
   d. “Qui Tam” –Private Citizens authorized to act as private attorney’s general to enforce law, as long as they knew what was going on, get to keep part of recovery

5. Making Sense of the Referral Fee Statutes Mark Hall
   a. Three purposes of stark act:
      1.) Prevent unnecessary services
      2.) Reduce charges
      3.) Reduce influence of financial considerations in referral decisions
   b. Notes problem in accessing fair market value of services

6. Two sources of law—both state and federal

7. Prosecutorial discretion heads off problem of many socially accepted and beneficial relationships violating felony statute
V. The American Health Insurance System and Its Reform
   A. History and Sources of Health Insurance in America
      1. US Health Care Coverage and Costs: Historical Development and Choices for the 1990's, Randall Bovbjerg, Charles Griffin, & Caitlin Carroll
         a. Pre-1929—largely fee for service out of own pocket, most care outpatient
         b. 1929-1940—rise of blue cross/blue shield. Fee for service and could choose any doctor.
         c. 1940s-1950s rise of workplace coverage
         d. 1960s-1970s incremental expansion of coverage as government entered to cover poor, disabled, aged—followed basic pattern of fee for service with patient choice of physician
         e. 1970s—entry of cost containment measures
         g. 1990s—rising costs, falling coverage
      2. Paying for Health Care, Thomas Bodenheimer & Kevin Frumbach
         a. Sources of Health Care Financing 1991
            1.) 22% Out-of-Pocket
            2.) 5% Individual Private Insurance
            3.) 27% employment based private insurance
            4.) 43% government financing
         b. Sources of Coverage
            1.) Uninsured 14%
               a) Out-of-pocket not good because need and cost predictable
            2.) Individual Private Insurance 9%
            3.) Employment based private insurance 52%
               a) Growth spurred during WWII to attract workers
               b) Insurance allows costs to be redistributed—either by community rating or experience rating
            4.) Government 25%
      3. Other ways insurers spread risk
         a. Medical underwriting—exclude preexisting conditions, excluding certain conditions and procedures, avoiding high-risk subscribers
         b. Loss of benefits a problem for many workers—new employer may have waiting period, exclusions.
         c. COBRA—employees must be allowed to continue at the group rate for up to 18 months after a qualifying event (job loss, reduction in hours, divorce, death, retirement, coming of age) but the employee pays the premiums up to 102%.
         d. HIPAA—health plans can not impose preexisting conditions limits beyond 12 months, and that is shortened if the employee had prior coverage.
         e.
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         g.
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<tr>
<th></th>
<th>Medicare</th>
<th>Medicaid</th>
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<tr>
<td># covered</td>
<td>40+ million</td>
<td>40 million</td>
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<td>cost</td>
<td>130 billion</td>
<td>100 billion</td>
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<td>Eligibility requirements</td>
<td>65+</td>
<td>&quot;categorically needy&quot; or &quot;deserving poor&quot;</td>
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<td>10 years + work or spouse (88%)</td>
<td>1. AFDC recipients—child or pregnant woman (some states have expanded to include &quot;medically needy&quot;—little bit over income restrictions) i.e. NY: 7.5 billion, TX 1.5 billion even though same # of people).</td>
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<td>--disabled (10%)</td>
<td>2. SSI recipients (27% of recipients, 73% of expenses) (65+, blind, disabled plus income and asset levels below certain amounts—some elderly try to &quot;spend down&quot; to take advantage of Medicaid too—rules have been tightened—should it be similar to bankruptcy rules?)</td>
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<td>--end stage renal disease 1%</td>
<td>Working poor usually not covered</td>
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<td>no income levels</td>
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<td>Model</td>
<td>Social security</td>
<td>AFDC, other welfare programs, SSI</td>
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<td>Administered</td>
<td>Similar to corporation that self-insures : US collects payroll taxes, Health Care Financing Administration oversees, but contracts with fiscal intermediaries. Used to be: fee for service model—doctor sends bill to intermediary and paid in full 1983—prospective payment—set prices for many different treatment “DRG”—now that more private insurers setting prices also, medicare looks better to doctors 3-5% administrative costs—private industry more like 15%+ (monopoly so lack most advertising costs)</td>
<td>Great latitude to states—benefit levels can vary Funded by feds, controlled by state Feds set minimum standards, after that up to state Some states using managed care—Oregon tried to cover everyone, then rationed care Can apply for waiver from minimum standards</td>
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<td>Benefit packages</td>
<td>Part A: Hospitals</td>
<td>Some overlap between groups—elderly and disabled Long term nursing home care No patient contribution/deductible—occasionally co-pay ½-1/3 of all births 40% of nursing home 40% of AIDS care has helped infant morality</td>
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<td>Part B: physicians services (Modeled after blue cross/blue shield)</td>
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<td>does not cover prescription drugs, dental, vision part A—deductible—can be up to $1000 part B—can have significant copayment up to 20% many have “medigap” coverage</td>
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<td>Financed</td>
<td>Payroll tax 1.5% +1.5%</td>
<td>Federal/state funding—fed will match state funds—depends on states economy</td>
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<td>Takeout much more than ever put in—increase in life expectancy, inflation, increased costs</td>
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<td>Provider issues</td>
<td>Gaps—most charges more than Medicare pays—can become participating provider—bill at Medicare rate, little or no out-of-pocket, get paid more quickly</td>
<td>Can’t bill any extras—exception: HMO copayments—have to set rates high enough so that there are enough doctors taking patients</td>
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B. Health Insurance Coverage Disputes
1. Bechtold v. Physicians Health Plan of Northern Indiana
   a. PHP committee recommended that bone marrow transplant be approved. PHP reversed committee.
   b. Held: As a matter of contract interpretation, the unambiguous language of the contract shows that they had the right to deny coverage. Plan has no obligation to reclassify procedures even if they have reserved that right.
2. Broken Back: A Patient’s Reflections on the Process of Medical Necessity Determinations Margaret Gilhooley
   a. Patient who broke her back was denied extra hospital stay by utilization review committee ended up benefiting from a stay in rehabilitation facility
3. Private insurance often tracks federal government—looking to what Medicare covers to determine “medically necessary” or “experimental”
4. Medicare/Medicaid also limits coverage to where medically necessary and denies coverage for experimental
5. Under ERISA, medically necessary and experimental more often construed in favor of the patient
### C. Provider Reimbursement Mechanisms

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<tr>
<th>Payee</th>
<th>Procedure</th>
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<th>Spell of Illness</th>
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<th>Time</th>
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<tr>
<td>Doc</td>
<td>Fee for Service—Bill per procedure. More itemized. Traditional model --different from auto or hurricane insurance—hurricane fits insurance model—unpredictable event, outside control of anyone associated with claim—insurer, policy holder, provider medical care different auto insurance—might be a little incentive to jack system—but limits health care—more bad incentive structures What if auto insurance was like health insurance? Had to find licensed mechanic, paid no questions asked—how would you treat differently—incentive to do more for car.</td>
<td>N/A</td>
<td>DRG, etc More global—fixed payment for problems. Doctor is losing some of the ability to set the price. Prospective payment—income higher based on # of procedures. Rate set by insurer or Medicare. Have schedule for procedure. Not trying to pay every cost—some may be more, some may be less.—getting at average costs for a given procedure which means that given doctor on given day might not get full payment—might be underpaid. Reputation/intangibles not taken into account. Medicaid—for states to set rates</td>
<td>Capitation Final incentive to give less care. Transfer of risk from insurer to provider group. Doctor agrees to join, each patient company pays x$. Primary physician makes referral. --May only be on hook for own care? No risk for referral services--true capitation—doctor bears risk for referrals too—pay out for referrals. Doctors might like—less invasive utilization review—more in charge of own income—can be more subtle. May have intermediary of physician practice group—which may incentivize with year-end bonuses for less care, etc. Some K have stop-loss clauses—if amount of care goes over a certain amount then risk reverts back to insurer—avoid catastrophic expenses</td>
<td>Salary—most physicians not on salary—compensation does not vary with # of patients. Staff Model HMO’s; emergency room doctors</td>
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<td>Hosp</td>
<td>FFS</td>
<td>Per diem</td>
<td>DRG, etc</td>
<td>Capitation</td>
<td>Global budget</td>
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1. **Reimbursing Physicians and Hospitals** Thomas Bodenheimer and Kevin Grumbach  
a. Most providers experience 4 or 5 types of reimbursement in single day
2. **Cost Based Reimbursement**  
a. **Health Plan** Alain Enthoven  
1.) Uncertainties implicit in medical care mean that health care does not fit typical insurance model—more subjective, choice, open-ended treatment means that financial incentives play a greater role
b. Memorial Hospital v. Bowen
   1.) Hospital chose more costly method of managing pharmacy and was denied reimbursement because its costs were out of line with other hospitals in the area.
   2.) Held: In determining whether costs are outline, the costs must be compared to hospitals with similar costs, offering the same type of pharmacy services.

c. Reasonable Cost Reimbursement for Inpatient Hospital Services under Medicare and Medicaid Stephen M. Weiner
   1.) “reasonable cost reimbursement” means that payment is calculated to reimburse hospitals for expenses in providing case, emphasizes whether costs fall into allowable categories and whether they are “substantially out of line” with other institutions
   2.) In actuality, ended up guaranteeing significant payments above actual cost in the form of accelerated depreciation amounts and a 2% cost-plus allowance.

3. Capitation Payment
   a. Reimbursing Physicians and Hospitals Thomas Bodenheimer and Kevin Grumbach
      1.) Capitation different in Britain—each general practitioner receives a fee per patient on their list.
         a) “Two Tier structure” of health plan and then the small number of doctors in private practice
         b) 20% of US HMOs use two-tier structure—physician bears cost of referring to specialist directly
      2.) “Three Tier” structures
         a) Physicians join in practice groups which spreads risk out among groups, use financial incentives such as returning surplus to decrease utilization
         b) Variation: Some practice groups receive capitated payments, yet reimburse individual physicians on fee-for-service basis
      3.) Payment per Time= Salary
         a) HMO bears risk, not physicians

D. Regulation of HMOs and Other Insurance/Provider Arrangements
1. Rise in Integrated Delivery Services
   a. Cover broader range of services—both inpatient and outpatient care
      1.) Three critical components of market: insurance, hospitals, physicians
      2.) Options when acquiring physician practices
         a) Could make them employees
         b) Could make equity partners
         c) MSO—acquire tangible assets of practice but doctors remain independent contractors
b. Unlike older networks, tend not to be as overlapping and nonexclusive

c. Beginning to incorporate insurance risk
   1.) Still question as to once doctors or hospitals enter the business of accepting the risk of bad outcomes as to whether they are insurers subject to state regulation
   2.) In MN top 20 employers banded together to self-insurer, state said would not regulate like health insurance
   3.) “downstream” risk contracting
       a) even where all risk is pushed downward from employers to managed care organization to providers—states often will not regulate the providers as insurance if they are satisfied that someone is meeting the state requirements

d. Different Degrees of Integrations
   1.) Full-Integration: Top down control of all components (i.e. staff model HMO)
   2.) Less integrated: each components remains separate entity but affiliated with others by contract or ownership (holding company) (network-model HMO).
   3.) Least Integrated: Loose contractual network, with no common ownership (i.e. PPO)

2. Health Maintenance Organizations Michelle Garvin
   a. Success stems from government promotion of HMOS and ability to control medical costs and manage care—incentive to keep people well
   b. Models
      1.) Staff Model—physicians paid salary
      2.) Group Model—HMO contracts with group practice paying captivated amount who employs or contracts with physicians
      3.) Independent Practice Association—contracts with individual physicians in independent practice or with associations or multi-specialty practice groups. Pay fee-for-service based on fixed schedule.
      4.) Network—care delivered by network of physicians and groups and possibly HMO health centers
      5.) Joint-venture. Might form separate physician hospital organizations (PHO) or three-way contracts with hospital, staff physicians and HMO
   c. Some states require that HMOS be tax-exempt non-profits
   d. State regulations authorize and regulate operation of HMOS, some states limit degree of risk providers and provider networks may assume
   e. HMO Act of 1973
      1.) Dual choice requirement—employer with more than 25 employees must offer HMO
      2.) Federally qualified HMO—comply with Act by:
a) Offering minimum benefit package  
b) Meet financial standards  
c) Have quality assurance program in place  
d) No preexisting conditions limits or refusal to enroll based on health care status  
e) Have grievance procedures  
f) Comply with community rating requirements  

E. Health Policy  
1. Universal Health Coverage  
a. The Right to a Decent Minimum of Health Care Tom L. Beauchamp & James F. Childress  
1.) Two Main arguments in favor  
a) Collective social protection  
   i. Other needs protected by government  
b) Fair opportunity  
   i. Societal health resources can be used to counter morally arbitrary disadvantaging effects  
2.) How to limit  
a) Right to equal access  
b) Right to decent minimum of care  
1.) Clinton plan aims: universal coverage, delivery system reform, cost containment  
2.) How to Pay:  
a) Raise new money  
b) Redistribute existing funds  
c. Health Care Financing in Selected Industrialized Nations: Comparative Analysis and Comment Deborah Chollet  
1.) Canada—public insurance covers most services, private insurance is available for services not covered. Financed by federal and provincial governments from general revenue, payroll taxes. Hospitals may be private or public, most physicians in private practice. Binding per diem rates and fee schedules.  
2.) Germany—1,200 individually funded and administered sickness funds for professional/trade groups. Financed individually by payroll tax, government pays for retired. Each plan negotiates with doctors and hospitals.  
3.) Great Britain—NHS comprehensive coverage for hospital and medical care, financed from general revenues, some services require user fees, owns most hospitals and most specialists salaried employers, Most general practitioners in private practice paid capitated amount.  
a) “queing” ration by waiting time to decrease utilization  
d. The Future of the American Health Care System Henry T. Greely
1.) Contrast between great strides and great gaps in coverage and rising costs
2.) Cost must be considered relative to quality
e. Why Conservatives don’t talk about America’s Health System
   Democratic Study Group
   1.) Health linked to socio-economic status, gender, race
   2.) Higher satisfaction rates abroad
f. Dangerous Medicine: A Critical Analysis of the Clinton Plan Doug Bandow
   1.) No better nation to become sick in—health affected by other US problems

2. Rationing and Cost Containment
a. Patient Power: Solving America’s Health Care Crisis John C. Goodman & Gerald L. Musgrave
   1.) Demand virtually unlimited
b. Making Medical Spending Decisions: The Law, economics, and ethics of Rationing Decisions Mark Hall
   1.) Medical needs are limitless because aging and illness are permanent conditions
   2.) Two key questions:
      a) Who should decide what care is not worth the cost
         i. Cost-sensitive decisions could be made by doctors, patients or third parties
         ii. Oregon plan—tried to ration to afford all citizens some level of Medicaid benefit
      b) What criteria of benefit should be used
c. Health Care Rationing and Disability Rights Phillip G. Peters, Jr.
   1.) Calculate effectiveness based on Quality-Adjusted Life-Years.
      a) Allows procedures to be compared based on expected benefit and cost effectiveness
   2.) Instead of excluding groups, exclude marginally effective care
   3.) Increased chance of discriminated against disabled: how to measure quality of life
      a) ADA potential roadblock to all rationing
d. Managed Competition and Its Potential to Reduce Health Spending Congressional Budget Office
   1.) Managed competition could reduce costs and utilization by making consumers pay costs of purchasing insurance other than least expensive
   2.) Regional organizations could oversee restructured insurance market and help consumers make better informed choices among standardized plans
   3.) Could limit subsidy to employers to encourage cheaper insurance
e. The Inevitable Failure of Current Cost-Containment Strategies: Why they Can Provide Only Temporary Relief William Schwartz
1.) Most of increase in hospital costs can be traced to: population growth, rising real input prices, increased intensity of services due to technological innovation.

2.) Risk that cost containment will cause innovation to suffer

3. Health Plan Alain Enthoven
   a. Choice between competition and regulation, also a choice about proper role of government
      1.) Risk of regulators being “captured” by the regulated

4. Different Influences on American Health Care
   a. Market
   b. Politics
   c. Moral principles
   d. Professional