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**Health Law Survey 2 Outline**

Prof. Barbara Evans, spring 2010; Law of Healthcare Organization and Finance - Furrow 6th

**I. INTRODUCTION:** Overview of Insurance and Managed Care (Furrow Pages 254-264);

1. Working Definitions:
   1. **Service Benefit Plans**: Formed by hospitals (later became Blue Cross) to pay hospitals for services provided. Charged community rated premiums.
   2. **Community rated premiums**: charge applied equally to all members of a community (community pricing).
   3. **Indemnity coverage**: Commercial insurers which indemnified insureds for service charges. Charged experience rated premiums.
   4. **Experience rating**: premiums priced based on cost of actually insuring a group based on past experience (risk subgroup pricing)
   5. **Managed Care Organization**: Health insurance structures that control the payment and livery of medical care; attempted to control the price, utilization, and quality of health care services. Response to double digit premium increases of 80’s & 90’s.
      1. More or less distributes risk between the provider and the insurer
      2. More or less uses administrative oversight to approve/deny clinical decisions.
      3. More or less requires insureds to use specified network of providers.
      4. HMO: limits members to network, capitation incentives, can use “staff” physicians or contract with independent network.
      5. Point-of-Service Plan (POS): Like HMO but allow insureds to go out of network if they share cost (copayment/deductible disincentives); often use gatekeepers.
      6. Preferred Provider Org. (PPO): Like POS but use FFS and utilization review
      7. Provider Sponsored Org. (PSO): Provider networks which contract directly w/ insureds (or employers) to provide service; use capitation.
   6. **Utilization Control**: Oversight of clinical care designed to minimize waste.
   7. **Gatekeeper Control**: Oversight of care by insured’s primary physician who has authority to make referrals to specialists.
   8. **Adverse Selection**: The phenomenon where those who are more likely to need medical care are more likely to get it, and only the type of insurance that best covers that care. This leads to an over-concentration of risk, which generates an increasing feedback loop.
   9. **Moral Hazard**: The phenomena where those w/ insurance tend to overutilize and act with less regard to cost.
2. Utilization Review**: Wickline v. State**;
   1. Summary: Patient sued Medi-Cal following amputation of leg as a result of premature discharge from hospital due to payor’s utilization review process. The Dr. requested that Medi-Cal cover keeping the patient at hospital for 8 days; they covered four. After discharge patient got a clotted blood vessel and infection; required amputation. The court held that the Dr. should have reiterated his request as the power to discharge the patient is his alone and it is his responsibility to do by the standard of care.
   2. RULE: Third party payors of health care services can be held legally accountable when medically inappropriate decisions result from defects in the design or implementation of cost containment mechanisms as, for example, when appeals made on a patient's behalf for medical or hospital care are arbitrarily ignored or unreasonably disregarded or overridden. However, the physician who complies without protest with the limitations imposed by a third party payor, when his medical judgment dictates otherwise, cannot avoid his ultimate responsibility for his patient's care.
   3. Utilization review traditionally concerned quality assurance and was done by hospital medical staff. Now it is about costs, done by insurance.
      1. Prospective utilization review process (cost containment)
         1. Dr. calls for procedure
         2. Nurse fills out approval form for transmission to HMO
         3. HMO representative received the form, contacted HMO consultant
         4. HMO consultant denied the procedure
   4. what bearing does the holding have on the doctor’s duty and state program liability?
      1. Doctor’s duty: to ensure that the patient is prescribed all medically necessary treatment, even if that means challenging the payor or prescribing out-of-pocket care.
      2. Payor liability: if the payor arbitrarily or unreasonably denies coverage so as to recklessly hinder the provision of medical services for which it is contracted it can be held liable for inadequate care.
3. kinds of utilization review
   1. Retrospective: third party payor reviewed the patient's chart after the fact to determine whether the treatment provided was medically necessary. If, in the judgment of the utilization reviewer, it was not, the health care provider's claim for payment was denied.
   2. Prospective: third party payor reviews the care request prior to treatment to determine whether the treatment proposed is medically necessary. If, in the judgment of the utilization reviewer, it is not, the insureds claim for treatment is denied.
   3. A mistaken conclusion about medical necessity following retrospective review will result in the wrongful withholding of payment. An erroneous decision in a prospective review process, on the other hand, in practical consequences, results in the withholding of necessary care, potentially leading to a patient's permanent disability or death.
4. “Cost Conundrum”, Atul Gawande, New Yorker: The escalation of cost in MacAllen due to overutilization incentive
   1. Potential remedies
      1. Remove the financial temptation from doctors: put them on salary
      2. Restrict the ability of doctors to benefit from referring patients to ancillary services.
      3. Factor patient evaluations of their treatment into the doctor’s review process.
      4. Do not offer bonuses to doctor’s for reducing costs of care.
5. **Overview: The Issue of Quality in Health Care**
   1. Defining Sickness (p 1- 35)
6. **Katskee** (p3)
7. Ins co. argued that appellant did not suffer from an illness because she did not have cancer. The court held that appellant suffered from a bodily disorder or disease and thus suffered from an illness as defined by insurance policy. Moreover, the court held that appellant's condition constituted illness within the meaning of the policy. The instant court held that appellee had not proffered any evidence disputing the premise that the origin of appellant's condition was in the genetic makeup of the individual, and that in its natural development it was likely to produce devastating results. In light of the plain and ordinary meaning of the terms "illness," "bodily disorder," and "disease," the court found that appellant's condition constituted an illness within the meaning of the policy.
   1. The policy contract defines what a “sickness” is, what treatment is “medically necessary”.
      1. If those terms are indefinite, the court will interpret.
   2. The definition of those terms can actively promote or inhibit coverage.
8. ISSUE: should “disease” include syndromes for which patient bears some responsibility (alcoholism, obesity)?
9. ISSUE: Illness v. Preexisting Condition – treatment of infertility covered as “disease”?
   1. Misconceptions re: Medical Care (p10)
10. If the doctor can’t identify an illness, precisely answer patient’s questions, and prescribe appropriate treatment that is incompetence or malpractice.
11. For each condition there is a “best” treatment and it is up to the doctor to know of and implement it. All else is waste, fraud, or under-service.
12. Medicine is an exact science with firm scientific bases for standard treatments.
13. Medical care consists of standard products that can be precisely described and meaningfully measured in standard units.
14. More care is better than less care.
    1. Defining and Assessing Quality (p 21 -24)
15. Structure Assessment
16. The resources (human, financial, physical) of the providers’ setting.
17. Powerful promoter of quality, but it can only assess quality of care through general tendencies and can frame the implementation of process assessment.
18. Process Assessment
19. Normative judgment of the providers’ procedures for the actual provision of care.
20. Most direct assessment; “standard of care”. However:
    * + 1. Weak objective basis for many processes.
        2. Emphasis on process leads to costly “defensive” medicine.
        3. Assessment may not account for more discrete elements of processes like personal interactions.
21. Outcome Assessment
22. Effects attributable to care provided. Justifies “evidence-based” medicine & pay for performance.
23. The array of factors affecting outcomes is so broad as to make this assessment imprecise and oversimplified. Doesn’t account for interpersonal elements of outcomes/satisfaction.
24. Resonates with smith v. heckler (p 150; See IV(c))
    1. FDA’s Role in Regulating Quality of Care
25. **Berry v. Cardiology Consultants** (p28) (FDA label is not conclusive on safe use)
26. Berry was prescribed drug for off-label use. He died. The drug was well accepted for off label use but, because of lack of financial incentive, the manufacturer never sought FDA review for that use.
27. The standard of care for this off label use was not label, but an algorithm that presented a rough medical consensus.
28. **Wyeth v. Levine** (supp) (absent direct conflict FDA not preemptive)
29. Summary: Levine was administered IV nausea meds off-label, in a manner that directly contradicted the safety labeling, by a nurse that never read the label. Wyeth claimed the FDA preempted the state-law COA. The court held that the FDA did not create an impediment to unilaterally strengthening the label warning.
30. Wyeth argued that the FDA role of approval of the label preempted the state’s duty to warn COA (conflict preemption)
31. Wyeth argued  it was impossible to comply with the state-law duty to modify labeling w/o violating federal law because stronger label wasn’t what was approved by FDA (preemption by impossibility)
32. Majority holding on preemption (REVIEW HANDOUT & REVISE)
    1. As for ordinary conflict preemption, there is no evidence of congressional intent to preempt state tort inadequate warning actions. Intent was consumer protection which is bolstered by state law.
       1. FDCA includes saving clause preempting state law only in case of “direct and positive” conflict.
    2. There is no preemption by impossibility because the FDA's regulation permits certain preapproval labeling changes that add or strengthen a warning to improve drug safety. There was no evidence the FDA would have rejected such a change.
33. The dissent criticized the holding as focusing on the issue of whether Wyeth had a duty to provide "an adequate warning” instead of whether it is the FDA or a state court that has the authority for determining the "adequacy" of warning.
34. Drug labeling, according to the dissent, is conclusive about how a drug can be used safely and effectively. Allowing a jury to judge adequacy of labeling conflicts with FDA authority, thus requiring preemption.
35. FDA labeling is not conclusive (Berry) or, in the absence of direct conflict, preemptive of state-law failure to warn causes of action (Wyeth).
    1. **FTCA Preemption Doctrine:** *Does federal regulation preempt state tort suits against federally regulated entity?*
36. First Principles
37. Legislative intent is the primary touchstone in preemption analysis.
38. In a field where state police powers have traditionally applied, the presumption is that congress has preempted no more than explicitly stated.
39. Express Preemption - What does the statute say? Does it plainly preempt state court suits?
40. Language preempting state “standards and requirements” preempts state tort suits.
41. Language just preempting state “standards” would bar state regulations but not tort suits.
42. ERISA §514
43. Implied Preemption – Court must draw inferences about intent to preempt
44. Conflict Preemption – If it would be impossible to comply with both the state tort law and the federal statute, the state law is preempted.
45. Field Preemption – If the federal regulation is so detailed and broad that it appears congress intended to “occupy the whole field” then there is no room for state laws to impose additional requirements through tort suits.
46. Minimal v. Optimal Regulation – Minimal federal regulation sets a floor and is not preemptive of additional state requirements through tort suits. Optimal regulation sets a floor and a ceiling and is preemptive.
47. ERISA §502
48. **Federal Tort Claims Act:** *Is the federal agency immune from tort suit, period?*
49. Prior to FTCA: Tort suits against fed gov not allowed
50. FTCA creates an exception allowing some tort suits, but subject to restriction. Requirements are:
51. On or after 1945.
52. For injury or loss of property, or personal injury/death
53. Caused by negligent or wrongful act or omission of any gov’t employee acting w/in scope of employment.
54. If a private person would be liable in those circumstances.
55. Money damages, without punitive or pre-judgment interest, are the exclusive remedy.
56. Exception to the exception bars suits:
57. Based on Ministerial Acts
    * 1. act/omission of gov employee exercising due care, in the execution of specific law/regulation which specifically instructs the agency/emplyee
      2. Negligence destroys the immunity provided by this exception
58. Based on Discretionary Acts
    * 1. Performing (or failing to perform) discretionary function on the part of a federal agency or gov employee.
      2. This exception only grants immunity for policy-oriented discretionary decisions (stops state-courts from second guessing federal policy).
         1. Policy decisions involve cost/benefit analysis, conflicting interest trade-offs, etc.
    1. Medical Care Quality Assurance
59. Medical safety model
60. Focused on individual error; high possibility of reprisal; error shameful; disincentive to investigate
61. Aviation safety model
62. Focused on systemic error; low probability of reprisal; error viewed as inevitable; incentive to investigate
63. Heinous, preventable medical errors
64. Sentinel Events: (JCo)
    1. “an unexpected occurrence involving death or severe physical/psych injury or risk thereof”
    2. Mandatory reporting; if reporting not done, hospital must investigate or risk loss of accreditation
       1. Root cause analysis
65. Never Events: Nat’l Quality Forum, States, CMS
    1. "Adverse events that are serious, largely preventable, and of concern to both the public and health care providers for the purpose of public accountability’
    2. All fees often waived if “never” event occurs.
66. Pay for Performance: absorption of losses
    1. Flat fee for procedure, no cost follow up care related to the procedure = internalize cost of error

**III.** **REGULATION OF HEALTH CARE PROFESSIONALS**

1. Food and Drug Administration Amendments Act of 2007
2. Allows FDA to place REMS (Risk Evaluation and Mitigation Strategies) restriction on drugs, effectively curtailing offlabel use and can mandate post-approval studies and labeling changes.
3. Use outside of REMS is unlawful; liability on manufacturer not provider.
4. Following REMS can bolster “regulatory compliance” defense to malpractice suits.
   1. Does not preempt state torts against providers prescribing outside REMS
5. Three methods of physician regulation
   1. Market restriction (licensing & discipline)
      1. Pro: Decisive means of removing incompetent practitioners
      2. Con: Self-regulation; Can be tool of the orthodoxy to inhibit innovation or stifle competition
   2. Market facilitation (consumer-value information like report cards & malpractice disclosures)
      1. Pro: Empowers consumer
      2. Con: unsophisticated consumer may not adequately synthesize available data to make informed choice
   3. Market channeling (certification by non-governmental organizations like JCO)
      1. Pro: Avoids onerous and overbroad state control
      2. Con: Can be a de fact delegation of traditional state power without public oversight
6. Tort law: regulation of quality through liability; subject to historical limitations
7. Physician Regulation
   * 1. Malpractice: Substandard care penalized by state court
     2. Credentialing: For quality or economic purposes hospitals will choose who is credentialed and what it entails.
8. MCO’s will also factor this in when reviewing network membership
9. Physician Licensure:
10. State controlled system for admission of doctors to practice medicine in the state. Quality control overseen through the state medical boards which may revoke license.
11. Judicial Oversight of medical licensure: States provide meaningful review of medical board decisions
    * 1. **Hoover Case** (p101): court overturned board’s revocation of license as against the weight of the evidence
12. SPECIAL ISSUE: Controversial narcotics prescribing
    1. Can involve state prescribing laws, state medical boards, Medicaid regulations, the FDA, and the DEA.

**I.** **HEALTH CARE INSTITUTIONS: REGULATION OF QUALITY**

1. Tort law: regulation of quality through liability; subject to historical limitations
2. Corporate Practice of Medicine Doctrine
   * 1. Traditional practice of medicine doctrine
        1. **Bartron v. Codington County** (supp)
           1. Docs associated into a clinic, which incorporated. Corp comprised of docs, not lay people.
           2. Corp’s inject the profit motive into professional practice, undermining professional ethic
           3. The doctors’ corp was therefore against public policy, and in violation of CPMD
        2. **Utah County v. Intermountain** (p615): Non-profits can get a pass on CPMD by charitable immunity
           1. Issue: Whether state law exempting from taxation hospitals meeting certain requirements, constituted an unconstitutional expansion of the charitable exemption.
           2. Majority: Hospitals no longer represent a charitable institution as they tend to be money-making ventures, do not relieve the state of a significant burden (state still pays Medicaid), and generally require patients to pay for treatment. Charity exemption is therefore denied.
           3. Dissent (*Majority View*): The hospital is a charitable institution because its income is used solely to further its charitable purposes, it does not turn away indigent patients, it relieves the government of a burden by its sheer existence (better than no hospital at all).
     2. Modern practice of medicine doctrine
        1. **Berlin v. Sarah Bush Lincoln Health Center**(p594) *Modern* CPMD
           1. Doctor sought to invalidate restrictive covenant. Trial court said the non-prof hosp violated CPMD. AppCt aff’d.
           2. The court declined to apply CPMD to licensed hospitals. The court also held that the public policy concerns, which supported the corporate practice doctrine, were inapplicable to a licensed hospital in the modern health care industry.
        2. What entities can actually employ doctors w/o violating CPMD? (In order of acceptance by states)
           1. Med schools, HMOs, non-profit hospitals, for profit hospitals.
        3. CPMD could be enforced by Atty Gen or Sec’y o State.
           1. More often it is a contracting party (doctor who wants to nullify employment contract)
     3. Texas practice of medicine doctrine
        1. **Flynn Bros. v. First Medical Associates** (supp)
           1. First, P’s partnered with doctor for med-services contract. That violates CPMD
           2. Then, doc formed corp and P’s were hired as the management company of the corp
           3. P’s essentially had full commercial control of doc’s license. This made doc a de facto employee, in violation of CPMD.
   1. Governmental and Charitable Immunity: Largely abolished; look to FTCA for relevant guidance
   2. Vicarious Liability: Just as the CPMD poses a risk to the hyper-active hosp, it is also a shield against vicarious liability. If the hosp cannot act in medical arena, liability harder to prove.
      1. Note the difference between vicarious liability/implied agency (de facto employee status) and apparent agency (unreasonably mislead to believe agent has authority)
      2. **Schloendorf Case** – 1914 (hospital immune from liability for doc’s negligence)
         1. The court held that the charitable hospital was immune from liability related to an unauthorized surgery conducted by its resident physicians, as the relation between the hospital and its physicians was not that of master and servant.
         2. True ground for hospital's exemption from liability is that the relation between a hospital and its physicians is not that of a master and servant. The hospital does not undertake to act through them but merely to procure them to act upon their own responsibility.
         3. Lastly, the court found that the hospital was not chargeable with a nurse's knowledge, as the nurse was not a servant of the hospital but a delegate of the surgeon to whose orders she was subject.
      3. **Bing Case** 1957 (overruled Schloendorf; did away with hospital immunity)
         1. The appellate division applied longstanding precedent in holding that the hospital could not be held liable for the hospital-employed nurses because the negligent act of not checking or changing the sheet stained with flammable material was a medical rather than an administrative act.
         2. The court noted that the administrative versus medical act distinction in the longstanding hospital immunity rule had resulted in inherent incongruity and that the policy reasons behind the rule no longer existed.
         3. The court abandoned the doctrine which accorded the hospital immunity for the negligence of its employees and held that the proper test for hospitals, whether charitable or profit-making, was whether the person who committed the negligent injury-producing act was a hospital employee and, if so, was he acting within the scope of his employment. Such a rule placed hospitals under the same test as other employers in negligence actions.
   3. Apparent agency: the agent's conduct causes 3rd party reasonably to believe that the agent has authority
      1. **Roessler v. Novak** (apparent agency)
         1. The patient was admitted through the hospital's emergency room. The radiologist performed scans of the patient's abdomen after the patient was admitted. The patient developed serious complications after surgery. He claimed the hospital was vicariously liable for the negligence of the radiologist.
            1. The radiologist worked for an independent contractor that provided radiological services to the hospital
         2. The hospital provided the patient with the services of the radiologist along with all of the other services the patient received while hospitalized. The patient accepted those services and did not retain his own specialist. Court found hospital vicariously liable for the radiologist's negligence under the doctrine of apparent agency.
      2. **Adamski v. Tacoma Hospital**
         1. The patient argued that the hospital was liable for the actions of the doctor and nurses that worked for it.
         2. The patient went directly to the hospital's emergency room and was given no choice respecting his physician. There was substantial evidence that the doctor who treated him was performing an inherent function of the hospital, a function without which the hospital could not properly achieve its purpose. A substantial and genuine issue of fact existed as to whether the relationship between the hospital and the doctor was that of principal and agent.
         3. A jury could have found that the hospital held itself out as providing emergency care services to the public and that the patient reasonably believed that the doctor was employed by the hospital to deliver that emergency room service. The court held that when the hospital undertook to provide medical treatment, the doctor employed to deliver that service for the hospital was an integral part of the total hospital enterprise.
      3. **Baptist Memorial Hospital System v. Sampson**, (apparent agency – TX)
         1. Respondent hospital system on a vicarious liability theory when ER physicians failed to properly treat his spider bite.
         2. The appellate court found a nondelegable duty for the negligence of its emergency room physicians. The supreme court rejected the imposition of a nondelegable duty and determined that the appropriate standard for liability required respondent to establish an apparent agency.
         3. The supreme court held that respondent had to show that the conduct of petitioner led respondent to reasonably believe that emergency room physicians were petitioner's employees and that she justifiably relied on that appearance.
   4. Agency by estoppel:  principal acts in such a way as to lead a 3rd party to reasonably believe that another is the principal's agent and the 3rd party is injured
   5. Direct Corporate Liability: negligent credentialing, negligence re: the facility, and the likelihood that hosp will be made party to malpractice actions.
      1. **Darling v. Charleston Hospital** (This case invented hospital liability for staff negligence)
         1. Plaintiff broke his leg and was treated at defendant's emergency room. His leg was put in a cast, but the cast cut off his circulation and he lost part of his leg. Plaintiff sued defendant for negligent hospital treatment and was awarded damages.
         2. Standards for hospital accreditation and the state licensing regulations demonstrated that the medical profession regarded it as both desirable and feasible that a hospital assume certain responsibilities for the care of the patient, contrary to defendant's assertion.
         3. The court found a jury could reasonably find negligence because the nurses did not test for circulation in the leg as frequently as necessary, that skilled nurses would have promptly recognized those conditions, and would have known that the condition would become irreversible in hours and informed the attending physician or hospital authorities. There was no dispute that defendant failed to review the doctor's work or require a consultation and a jury could have reasonably found that a failure to do so was a negligent act.
      2. **Johnson v. Misericordia**
         1. A surgical procedure was unsuccessfully performed on the patient at the hospital. The patient alleged that the hospital negligently selected the doctor who performed the procedure.
         2. The court ruled in favor of the patient. It held that the hospital had a duty to exercise due care when selecting its medical staff. The failure to investigate an applicant's qualifications for the staff privileges requested gave rise to a foreseeable risk of unreasonable harm.
         3. The patient only had to prove that the hospital did not make a reasonable effort to determine whether the doctor was qualified to perform orthopedic surgery. Under the doctrine of constructive knowledge, the hospital at a minimum was charged with having knowledge of that information which could readily have been obtained if only its personnel had contacted the hospitals referred to in the doctor's application.
   6. Blum Article: Feng Shui and the Restructuring of the Hospital (supp)
      1. Does three legged stool (admin, med-staff, trustees) harmonize with the regulatory environment of patient safety and quality? He proposes a) change in bylaws to focus on quality assurance; b) creating institutional department to regulate quality; or c) completely redistributing power between the 3 parts.
3. Certificate of Need Regulations (CON): Affects quantity of healthcare facilities, not quality.
   1. Certificates of Need are required in many jurisdictions to get state permission for undertaking construction or renovation of healthcare facilities.
   2. **Statewide Health Coord. Council v. Gen. Hosps. Of Humana** (supp)
      1. Corp sought to build a hospital in an area where the bed-to-person ratio established by federal and state regulations had been exceeded. State agency granted the corp's application. The court reviewed.
      2. The court held that the hospital-bed-to-person ratio was a maximum limit that could be exceeded only if the circumstances fell within the ambit of specific exceptions.
      3. The court held that there was no showing that the circumstances at issue fell within any of the listed exceptions. Thus, the agency was without authority to grant the corporation's application.
4. Regulatory Systems: setting standards, inspection, and sanction
   1. Certification (Medicare/Medicaid, etc); often reliant upon accreditation
      1. Federal quality oversight of care of patients receiving treatment paid through those programs.
      2. Layers of authority: Statute (158) > Rule / Regulation (161) > Guidance (161)
      3. Regulation through reimbursement
         1. If a hospital participates in a state or federal reimbursement plan then there will be strings attached. This is how Medicare regulations are enforced.
      4. EMTALA:
         1. Individuals needing emergency care must receive a medical screening examination to determine whether emergency exists and cannot be delayed to inquire about payment.
         2. Emergency must be resolved or stabilized prior to discharge/transfer.
         3. If the hospital does not have the capability to treat the condition, the hospital must make an "appropriate" transfer. Hospitals with specialized capabilities must accept such transfers.
      5. **Smith v. Heckler** (150) (facility-oriented v. patient-oriented care management)
         1. P sought to improve awful conditions in nursing homes funded by Medicaid. P claimed Secretary of HHS was required to ensure high standard of care through Medicaid certification.
            1. If state wants to get Medicaid funding it must submit a medical assistance plan to the secretary for approval. The state agency must maintain the standards of the facilities where Medicaid recipients receive treatment and ensure high quality. Quality shall be ensured by a system of review.
         2. Federal law gives secretary authority to “look behind” state’s determination of quality and make its own determination.
            1. The secretary has chosen to use a survey/certification method to enforce state compliance.
         3. The states conduct a survey of the facility and the secretary certifies the state’s plan based on that survey.
         4. P argued that the scheme was facility-oriented 9 focused on the ability of the facility to provide care) rather than patient-oriented (focusing on the care actually provided).
         5. The court held that due to the Medicaid acts focus on the care which patients actually receive, the federal delegation of authority in overseeing the quality of state facilities to the secretary, and the implementation of that authority in the “look-behid” provision which allows the secretary to actively inform himself of conditions at the facility; that the secretary has a duty to regulate in a patient-oriented scheme and a facility-oriented scheme was an abdication of that duty.
            1. The secretary must promulgate and enforce a patient-oriented scheme of state compliance.
      6. **Cospito v. Heckler** (supp - important)
         1. Patients in psychiatric hospital whose medicare, medicaid and SSI benefits were terminated when hospital lost its JCo accreditation, and as a result, its certification by HHS. They brought suit challenging loss of their federal benefits.
         2. The Patients argue that in the case of psychiatric hospitals, the statute places JCAH accreditation in a position of ascendancy over approval by the Secretary, thus leading to the question of unconstitutional delegation to a private group.
         3. Since, in effect, all actions of JCAH are subject to full review by a public official who is responsible and responsive to the political process, we find that there has been no real delegation of authority to JCAH.[FN29](http://web2.westlaw.com/result/documenttext.aspx?rp=%2fFind%2fdefault.wl&sv=Split&service=Find&rlti=1&cxt=DC&ifm=NotSet&n=1&mt=208&fn=_top&vr=2.0&rlt=CLID_FQRLT7344729291371&pbc=3F1E7F52&cite=742+F.2d+72&cnt=DOC&scxt=WL&rs=WLW9.11&ss=CNT" \l "B029291984139066#B029291984139066) See [Todd & Co. v. SEC, 557 F.2d 1008 (3d Cir.1977)](http://web2.westlaw.com/find/default.wl?tf=-1&rs=WLW9.11&serialnum=1977122779&fn=_top&sv=Split&tc=-1&pbc=1C99AB48&ordoc=1984139066&findtype=Y&db=350&vr=2.0&rp=%2ffind%2fdefault.wl&mt=208) (where actions of private organizations were subject to review by wholly public body, no unconstitutional delegation has occurred). We therefore affirm the district court in granting judgment to the defendants on this issue.
         4. The Court held that: (1) patients were not denied procedural due process; (2) certification procedure did not deny patients equal protection; (3) termination of social security benefits for patients in decertified hospitals did not violate substantive due process; and (4) medicare and medicaid provisions did not improperly delegate authority to commission.
   2. Hospital Licensure;
      1. Licensing statutes and regulations specify basic services and functions which must be provided by an acute care facility (must have ER, e.g.)
   3. Hospital Accreditation:
      1. “A self & peer assessment used by orgs to assess their performance in relation to established standards, and to implement ways to continuously improve”
      2. Parallel issues around evidence-based medicine, quality assurance and medical ethics, and the reduction of medical error is a key role of the accreditation process.
      3. Joint Commission is the predominate US accreditation org.
         1. accredits over 17,000 health care organizations and programs
         2. Majority of states condition licensure and receipt of Medicaid reimbursement on JCo accreditation.
            1. JCo certified hospitals are deemed to be in compliance with Medicare.
            2. Replacing government oversight with private accreditation can lead to lax enforcement because subscription is voluntary and must be enticed.

**V. LIABILITY OF MANAGED CARE ORGANIZATIONS**

1. Background of Health Coverage: The rise of employer-sposored health insurance
   1. Pre WWII, most healthcare coverage was commercial non-profit (BlueCross Blue Shield)
   2. Post WWII, coinciding w/ rising healthcare costs, the fed gov’t decided not to socialize health insurance
      1. Instead it provided that benefits could be negotiated as wages, and that benefits would not be taxable as income.
   3. In 1974 exempted employer-sposored health plans from state regulation (through ERISA)
      1. Crippled state market-mechanisms for health coverage
   4. In 1992 required employers to account for future liabilities of coverage
      1. Tidal wave of red ink caused a decrease in coverage.
   5. Decrease in employer coverage and escalating costs led to rise of Managed Care Organizations
2. Contract Liability of Private Insurers and Managed Care Organizations
3. **Katskee** (p3)
4. The policy contract defines what a “sickness” is, what treatment is “medically necessary”.
5. If those terms are indefinite, the court will interpret.
6. The definition of those terms can actively promote or inhibit coverage.
7. ISSUE: should “disease” include syndromes for which patient bears some responsibility (alcoholism, obesity)?
8. ISSUE: Illness v. Preexisting Condition – treatment of infertility covered as “disease”?
9. Tort Liability of Managed Care Organizations
10. Vicarious liability
11. Key concepts
    1. MCO encompasses a diverse array of entities which present varying degrees of liability.
    2. Vicarious liability is applied more harshly to MCO’s than hospitals b/c MCO patients have less control than hosp patients.
12. **Petrovich** (p269)
    * + 1. Plaintiff alleged that HMO was vicariously liable for the negligence of its independent-contractor physicians under agency law, under both the doctrines of apparent authority.
        2. The apparent authority doctrine imposed vicarious liability on HMO. There was no dispute that the coverage agreements were unknown to plaintiff, they could not be used to defeat her apparent agency claim.
        3. Defendant held itself out to plaintiff as the provider of her health care, without informing her that the care was actually provided by independent contractors. Plaintiff had no choice of health plans and was required to obtain primary medical care from one of defendant's primary care physicians. There was a reasonable inference that plaintiff relied upon defendant to provide her health care services.
        4. Plaintiff presented adequate evidence to support a finding that defendant exerted sufficient control over plaintiff's doctors as to negate their status as independent contractors.
13. **Pagarigan v. Aetna** (p279)
14. Nursing home malpractice / elder abuse case.
15. Duty of care in selecting independent contractors.
    * + - 1. Something beyond incentives to reduce quantity of care is required to demonstrate breach of the standard of care.
16. Direct institutional liability (corporate negligence)
17. **Shannon v. Mcnulty** (Negligent provision of services)
18. Plaintiff husband and wife brought an action for medical malpractice against HMO **and** doctor for negligently failing to timely diagnosis and treat signs of pre-term labor and alleged defendant HMO was vicariously liable for negligence of its nurses for failing to respond to plaintiff wife's complaints and refer her to a physician.
19. After a harm analysis the court found that the evidence was sufficient to allow the case to go to the jury on the theory of corporate liability against defendant HMO because it had a duty to oversee all persons who practiced medicine within its walls as to patient care.
20. The court found that the duties of a hospital in regard to corporate liability applied to defendant HMO when it provided health care services. The court found that there was sufficient evidence that defendant HMO had failed to exercise reasonable care in the rendering of telephone triage services.
21. Other sources of liability
22. Negligent selection of providers: just like hospital credentialing but stronger for MCO because of diminished control for individual
23. Failure to supervise/control staff:
24. Physician incentive systems
    1. **Pegram v Herdrich** (p360; SupCt - Note also for ERISA analysis)
       1. Respondent claimed that decision to delay her treatment was driven by HMO’s self-interest in increasing their incentive bonuses, in violation of petitioner's fiduciary duty under ERISA. The question on appeal was whether treatment decisions made by petitioner, acting through its physicians, were fiduciary acts within the meaning of ERISA. the court held that they were not.
       2. It was not for the court to draw a line between good and bad HMO's by making judgments about socially acceptable medical risk. Congress did not intend petitioner or any other HMO to be treated as a fiduciary to the extent that it made mixed eligibility decisions acting through its physicians. The federal judiciary would be acting contrary to the congressional policy of allowing HMO organizations if it were to entertain an ERISA fiduciary claim portending wholesale attacks on existing HMO's solely because of their structure, untethered to claims of concrete harm.
       3. ERISA Fiduciary Standard: Person with discretionary authority in management of plan assets has duty to act for exclusive purposes of providing plan benefits to members and defraying plan costs.

**VI. Regulation of Insurance and Managed Care**

1. Traditional State Regulation of insurance
   1. Despite ERISA, the states remain primary regulators of insurance provided by employers; as well as all health plans not covered by ERISA.
      1. States ensure fiscal solvency of insurers and approve policy forms,
      2. States did not traditionally regulate rates, underwriting practices, (except BlueCross/BlueShied). This is changing, however, to ensure broader access to insurance.
         1. States tend to distinguish policies based on group size (individual, 2-50, 50+)
   2. **Mass Gen Law**, Pg 311; HIGH PRIORITY – this kind of stuff regulated HMO’s to death
      1. Contains just about every reform implemented in recent push to manage MCO’s
         1. Increase communication w/ insureds (including grievance & appeals process)
         2. EMTALA definitions
         3. Mandatory emergency coverage by HMO’s (including use of 911); state mandates are common and often include preventative care like mammograms. Almost all states mandate coverage of emergency care.
         4. Consumer Protections with statutory definitions for policy terms (including medical necessity, which is done in about half of the states)
         5. Protection for providers from discrimination due to his explanation of coverage to insured
            1. But can contractually prohibit confidential compensation terms
         6. Prohibition against certain indemnifications
         7. Mandatory explanation of benefits, network details (specialty, reimbursement plan, location, etc) costs, criteria for rescission or disenrollment, rates of voluntary disenrollment, grievance/appeal process, quality assurance/utilization review practices, excluded prescriptions, and contact info.
         8. Madatory reporting of insured satisfaction, costs, and grievances
         9. Prohibition against inducing providers to improperly limit treatment (this law, as do all others that contain this provision, exclude captiation)
         10. Satisfaction surveys
         11. Many others
      2. Note Hyman’s perspective (p329) that MCO’s have lowered costs while keeping individual satisfaction high and quality above that of the fee-for-service smorgasbord. Unpopularity is due to over-hyped horror stories and lack of sympathy for insurance companies.
2. Utilization Control Procedures
   1. Utilization Review: Case by case evaluations of to determine necessity/quality of treatment/coverage
      1. OLD: retrospective. Had limited value as cost containment b/c money already spent
      2. NEW: prospective & high-cost-case oriented; effective as cost-containment
   2. Practice pattern review (as opposed to case by case)
   3. Gatekeeper: coverage decisions delegated to primary care doc, motivated to control cost by $$ incentives
   4. 44 states require independent review of coverage determinations
3. Provider Incentives for reduction of coverage costs
   1. Capitation (traditional incentive)
      1. Provider receives fixed fee for services and assumes the risk that his actual cost of providing them may be higher or lower than the fee.
      2. This forces the provider to internalize some of the risk, which may lead to underservice that is impossible to quantify or even explicitly identify.
         1. Some responses to this problem: limits on how much provider pay is at risk by capitation, regulating the size of population throughout whom this risk is spread, requiring stop-loss insurance.

**VII. Federal Regulation: ERISA Preemption and State Managed Care Liability \*\*\***

1. ERISA
   1. Covers
      1. Applies to employee pension, health, and benefits plans established or purchased by private employers
      2. Congress passed ERISA to insure that employee benefit plans would be regulated as “exclusively a federal concern.” The goal of ERISA preemption “was to avoid a multiplicity of regulation in order to permit the nationally uniform administration of employee benefit.”
   2. Basically
      1. Provides detailed substantive requirements for employee benefit plans
      2. Provides few substantive requirements for health plans
      3. Requires health plans to disclose information to covered individuals, meet fiduciary duty standards, provide a procedure to resolve disputes with the plan
   3. PREEMPTION:
      1. Section 502: Complete preemption; preempts claims if the issues are:
         1. Whether the plaintiff is eligible to bring a claim under ' 502(a);
         2. whether the plaintiffs cause of action falls within the scope of an ERISA provision that the plaintiff can enforce via ' 502(a); and
         3. whether the plaintiffs’ state law claim cannot be resolved without an interpretation of the contract governed by federal law.
            1. When all three factors are present, the state law claim is an ERISA claim under 502(a).
      2. Section 514: Express preemption
         1. Basic rule: ERISA preempts state law/regulation relating to employee benefit plan
            1. A state law relates to an ERISA-covered plan if the law specifically refers to such a plan; acts immediately and exclusively upon the plan; if the plan's existence is essential to the law's operation; or if it has connection or reference to such a plan

There is a split as to how much reference meets the “relates to” threshold

mandating benefits to be offered by plans;

mandating the manner in which plans are administered or binding plan administrators to a particular choices of substantive coverage; or

State law not affecting ERISA principals (employer, fiduciaries, or employees) is likely to survive

* + - * 1. If a claim can be brought under ERISA, it is preempted
      1. Savings clause: Exception to basic rule
         1. ERISA does not preempt general state regulation of insurance.

A state law regulates insurance if it is specifically directed toward entities engaged in insurance and it substantially affects the risk pooling arrangement between the insurer and the insured.

Any willing provider statutes do relate to ERISA plans beyond an indirect economic effect, but can usually avoid preemption through the savings clause

* + - 1. Deemer clause: Exception to exception
         1. : Employers that self-insure (bear the risk of insuring employees) cannot be deemed to be “insurers” for purposes of state regulation.
    1. Statutory Exemptions
       1. Pre-ERISA plans (pre-1975); Insurance/Banking/Securities laws; Other federal laws;
  1. **Rush Prudential (p340)**
     1. Patient sought independent medical review of her claim, as provided for in the Illinois statute. The Court held that the Illinois statute was a law "directed toward" the insurance industry, and an insurance regulation under a commonsense view, thus it was not preempted by ERISA.
     2. The Court rejected the HMO's arguments holding that the state statute did not enlarge a claim beyond the benefits available in any action brought under ERISA.
     3. The Court noted that the state statute bore a closer resemblance to second-opinion requirements than to arbitration schemes. The state law operated before the stage of judicial review and its effect was no greater than that of mandated-benefit regulation.
     4. What was the pertinent nature of the statute in that case – it required when utilization review had effect of denying care to insureds the state mandated independent review of decision.
        1. This decision occurred late in the evolution of ERISA review; court struggled very hard to find that action not preempted due to popularity of that legislation.
        2. Court used 502 preemption analysis.
           1. Question: is the review duplicative of ERISA remedy? Court says it is NOT a re-adjudication of the claim (which would be preempted). Analogizes to second opinion which is not re-adjudication. State’s argument that it is general insurance regulation which is saved from preemption.
           2. Note that there is a trend towards finding things saved from preemption to help state statutes survive.
     5. RULE: state statute is preempted if it creates additional remedies outside of ERISA. ERISA is a “field preemption” law.
        1. This rule should probably have controlled Rush; but the court really wanted to save the statute
  2. **Retail Industries vs. Fiedler** p354; MD attempted to pass law regulating Wal-Mart’s employee benefits plan
     1. The Act required employers with 10,000 or more Maryland employees to spend at least 8 % of their payroll on employees' health insurance costs or pay the amount their spending fell short to the state. WalMart was subject to this minimum spending requirement.
     2. On the merits, the court agreed with the district court that the Act was preempted by ERISA. The only rational choice for employers under the Act was to structure their ERISA health care benefit plans to meet the minimum spending threshold.
     3. Because the Act effectively mandated that employers structure their employee health care plans to provide a certain level of benefits, the Act had an obvious "connection with" employee benefit plans, and it was preempted by ERISA. Accordingly, the court upheld the district court's ruling granting summary judgment in favor of the association.
  3. **Blue Cross v. Travelers:** Ushered in narrow preemption to preserve states ability to regulate
     1. Travelers involved an ERISA challenge to three separate surcharges imposed upon state regulated hospital rates. The Supreme Court found that the impact of the hospital surcharges imposed by New York State on an employee benefit plan was too attenuated to be pre-empted under ERISA.
     2. ERISA preemption is only triggered by state laws that dictate or restrict choice of plan benefits or plan administrative structures. A state laws indirect economic impact on the price of benefits does not trigger preemption because it does not mandate plan choices, it simply influences a plan's decisions.
     3. Travelers will allow a state law to impact employee benefit plans regulated by ERISA without being preempted so long as the law has an "indirect economic effect" on the plan. The effect will be deemed direct if one of two scenarios is present. First, the law will be deemed direct of the effect of the law is to bind the decision of the plan administrator. Second, the law will be deemed direct if the law provides for variation in the benefits provided by the plan which are inconsistent with federal law.
  4. **Kentucky Ass'n of Health Plans, Inc. v. Nichols,**:
     1. In 1994, the Kentucky General Assembly enacted the Kentucky Health Care Reform Act. The Act contained an "Any Willing Provider" provision that stated: "Health care benefit plans shall not discriminate against any provider who is located within the geographic coverage area of the health benefit plan and is willing to meet the terms and conditions for participation established by the health benefit plan." Health Plans filed suit claiming Act was preempted by ERISA.
     2. While a mere reference to an ERISA plan, without more, may not be enough to cause preemption, Supreme Court precedent shows that if such a reference is combined with some effect on those plans, such as singling them out for different treatment, preemption will result. Court conclude that Kentucky's AWP statutes "relate to" ERISA plans and are therefore preempted, unless they are found to be statutes that regulate "insurance" under the savings clause.
     3. Under the Court’s holding, a state law is deemed to regulate insurance if it (1) is specifically directed toward entities engaged in insurance and (2) substantially affects the risk pooling arrangement between the insured and the insurer.
  5. **Aetna v. Davila on pages 372-80.** 
     1. Texas is the first state to address head on the perceived problem with managed care entities limiting access to healthcare through treatment decisions. The Texas Health Care Liability Act allows an individual to sue a health insurance carrier or MCO for damages resulting from negligent treatment decisions.
     2. Respondents both suffered injuries allegedly arising from the HMOs' decisions not to provide coverage under ERISA-regulated benefit plans for certain treatment and services recommended by respondents' treating physicians. Respondents alleged that the HMOs failed to exercise ordinary care in the handling of coverage decisions, in violation of a duty imposed by the Texas Health Care Liability Act (THCLA).
     3. The Supreme Court determined that respondents' causes of action fell within the scope of, and were completely preempted by, ERISA § 502(a)(1)(B). The duties imposed by the THCLA in the context of respondents' cases did not arise independently of ERISA or the plan terms.

1. Beneficiary remedies provided by ERISA 502(a) (p339)
   1. each subsection of ERISA ' 502(a), 29 U.S.C. § 1132(a), describes both a cause of action and the remedies available under that cause of action
      1. Statutory penalties authorized in certain circumstances by Section 502(c) which can be collected in a suit under Section 502(a)(1)(A).
         1. civil penalty on a plan administrator who fails, among other actions, to furnish within 30 days after a request by a participant or beneficiary, documents required to be furnished by ERISA
      2. Claims relating to benefits under Section 502(a)(1)(B).
         1. an action by a participant or beneficiary: to recover benefits due 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
      3. Remedies for breach of fiduciary duty obtainable under either
         1. Section 502(a)(2) – suit on behalf of plan; Section 502(a)(2) provides a cause of action by a fiduciary to obtain “appropriate relief: under Section 409 to redress violations of the ERISA fiduciary responsibility provisions.”
         2. 502(a)(3) - cause of action by a participant, beneficiary or fiduciary to enjoin an act which violates a provision of ERISA or the terms of the plan, or to obtain any other equitable relief;

**VIII. Access to Care And COST OF CARE**

1. **The Obligation to Provide Care** 212-16, 225-39
2. **Burditt v. US. Dept of Health and Human Services**;IMPORTANT; probably will have *similar* fact pattern
   1. The federal agency responsible for administering Medicare assessed a fine against the physician for violating EMTALA; the physician had refused to treat a Medicare patient in active labor and had signed a transfer order without specifying the required reasons to justify the transfer. EMTALA compliance is strict, and deviation from the statute puts you in violation.
   2. The court concluded that the doc violated EMTALA and government regulation under EMTALA was not an unconstitutional taking without just compensation because only hospitals that voluntarily participated in the federal government's Medicare program had to comply with EMTALA.
3. EMTALA is on pg 226
   1. **Know the elements of a successful EMTALA claim**
      1. Failure to screen for emergency condition; or
      2. Failure to stabilize the emergency condition (or labor)
      3. Failure to appropriately transfer emergency patient, if necessary
         1. Request for transfer in writing (with informed consent)
         2. Physician certified that benefits of transfer outweigh the risks
   2. Penalties
      1. $50k plus any state law PI damages
4. Current Healthcare Reform
5. New requirements of states
   1. Expand Medicaid to all non-Medicare-eligible individuals under age 65 (children, pregnant women, parents, and adults without dependent children) with incomes up to 133% FPL based on modified adjusted gross income. All newly eligible adults will be guaranteed a benchmark benefit package that meets the essential health benefits available through the Exchanges.
   2. To finance coverage for the newly eligible, states will get the federal medical assistance percentage (FMAP)
      1. 100% federal funding for 2014 through 2016, 95% federal financing in 2017, and 90% federal financing for 2020 and subsequent years.
   3. In addition, increase Medicaid payments in fee-for-service and managed care for primary care services provided by primary care doctors to 100% of the Medicare payment rates for 2013 and 2014. States will receive 100% federal financing for the increased payment rates.
   4. Require states to maintain current income eligibility levels for children in Medicaid and the Children’s Health Insurance Program (CHIP) until 2019 and extend funding for CHIP through 2015. CHIP-eligible children who are unable to enroll in the program due to enrollment caps will be eligible for tax credits in the state Exchanges.
6. **Medicare (True False & Multi-Choice on FINAL),**
7. Medicare Funding & Purposes (FYI: it is not means tested):
8. Part A: Hospital Insurance – payroll taxes which accumulate in trust fund;
9. Part A covers inpatient hospital stays and some skilled nursing care.
10. Pays out only on strict calendar schedules, if time limits exceeded Part A stops paying.
11. Payments based on prospective cost schedule; The actual allotment of funds is based on a list of diagnosis-related groups (DRG). The actual amount depends on the primary diagnosis that is actually made at the hospital. There are some issues surrounding Medicare's use of DRGs because if the patient uses less care, the hospital gets to keep the remainder. This, in theory, should balance the costs for the hospital. However, if the patient uses more care, then the hospital has to cover its own losses. This results in the issue of "upcoding," when a physician makes a more severe diagnosis to hedge against accidental costs.
12. Part B: Medical Insurance – 25% paid by enrollee premiums, rest by taxes
13. Part B helps pay for some services and products not covered by Part A, generally outpatient; covers some preventative care.
14. Physician billing: Akin to fee-for-service
15. Complex rules are used to manage the benefit, and advisories are periodically issued which describe coverage criteria. On the national level these advisories are issued by CMS, and are known as National Coverage Determinations (NCD). Local Coverage Determinations (LCD) only apply within the multi-state area managed by a specific regional Medicare Part B contractor
16. Part C: Medicare Advantage Plans – some payment by enrollee premiums, rest by taxes
17. Uses capitation and network coverage
18. Part D: Prescription Drug Plans - some payment by enrollee premiums, rest by taxes
19. Anyone with Part A or B is eligible for Part D.
20. Medigap
21. Some people elect to purchase a type of supplemental coverage, called a Medigap plan, to help fill in the holes in Original Medicare (Part A and B)
22. hospital v. physician incentives (incentive analysis on the above parts should also be done)
23. Hospitals can improve profits by refusing to treat those conditions which do not have a favorable PPS
24. Docs can improve profits by upcoding
25. **Pay for performance** incentive (441): subject to dangerously oversimplified outcome-oriented analysis
    1. It is very difficult to quantify qualitative outcomes or account for their causes. That leaves P4P on a shaky foundation.
26. Pathways to Medicare coverage (p429)
27. Request national coverage determination (NCD) or local coverage determination (LCD).
28. Appeals are made to Departmental Appeals Board. Harmed benificiaries are only ones with standing to appeal coverage determination.
29. **Medicaid**
30. Comparison with Medicare
31. Medicare is an entitlement program funded entirely at the federal level. It is a social insurance focusing primarily on the older population. Medicare is a health insurance program for people age 65 or older, people under age 65 with certain disabilities, and people of all ages with end stage renal disease..
32. Medicaid is a program that is not solely funded at the federal level. States provide up to half of the funding for the Medicaid program. In some states, counties also contribute funds. Unlike the Medicare entitlement program, Medicaid is a means-tested, needs-based social welfare or social protection program rather than a social insurance program. Eligibility is determined largely by income. The main criterion for Medicaid eligibility is limited income and financial resources, a criterion which plays no role in determining Medicare coverage. Medicaid covers a wider range of health care services than Medicare.
33. Eligibility (Means tested against federal poverty level)
34. Medicaid is a joint federal-state program that provides health insurance coverage to certain categories of low-income individuals, including children, pregnant women, parents of eligible children, and people with disabilities.
35. Medicaid is available only to people with limited income.  You must meet certain requirements in order to be eligible for Medicaid. Medicaid sends payments directly to your health care providers.
36. Mandatory Eligibility Groups
37. Limited income families with children
38. Supplemental Security Income (SSI) recipients
39. Infants born to Medicaid-eligible pregnant women.
40. Children under age 6 and pregnant women whose family income is at or below 133% of the Federal poverty level.
41. Certain people with Medicare (dual eligibility); and
42. Optional Eligibility Groups
43. Infants up to age one and pregnant women not covered under the mandatory rules whose family income is below 185% of the Federal poverty level;
44. Optional targeted low-income children;
45. Certain disabled adults with incomes above mandatory coverage, but below Federal poverty level;
46. Children under 21 who meet income requirements for Aid to Families w/ Dependent Children;
47. Institutionalized individuals with limited income and resources;
48. Persons who would be eligible if institutionalized but have home care by waiver;
49. Recipients of state supplementary payments;
50. Tuberculosis-infected persons who would be financially eligible for Medicaid SSI; and
51. Certain low-income, uninsured women in need of breast cancer treatment.

**IX. STRUCTURE OF THE HEALTH CARE ENTERPRISE AND PROFESSIONAL RELATIONSHIPS IN HEALTH CARE ENTERPRISES**

1. **Staff Privileges and Hospital-Physician Contracts**
2. Hosp curtails existing docs privileges
3. Individual doc: Doc with high death rate finds privileges curtailed, eg sokol case
4. **Sokol v. Akron Med Ctr. P501**
   * + 1. Cardiac surgeon with unreasonably high mortality rate (even considering that he was a death’s door doctor) has had his privileges revoked by hospital. He sued to have the hospital enjoined from removing his privileges, arguing insufficient notice. The court felt that the hospital had abided by the due process provisions of its bylaws and had given the doctor adequate notice of his termination. (contract status)
       2. *Note: Status of the medical bylaws – some states treat them as contractual obligation, others give them somewhat less weight.*
       3. *Note: What is the level of judicial review – if allowed at all, most states are very deferential to the hospital. (arbitrary & capricious)*
5. Group of docs: ER doctor group gets cut out in favor of outsorcing ER duties
6. Hosp curtails prospective docs privileges
   1. Due process generally limited to what is in the bylaws, some states will go above and beyond (common law fairness). In NH and a few others, that is derived from quasi-public interest / natural monopoly theory (small minority view). Is this scenario analogous to doc who wants to get on MCO? How are situations alik and different (note potman and harper)
7. **Mahan v. St. Lukes 514**
8. physicians, filed suit against hospital seeking a permanent injunction for appellant's decision to close its staff with respect to physicians requesting privileges for certain procedures.
9. When appellant made its decision to close the medical staff, it was acting within its powers under its corporate bylaws. The decision was a reasonable administrative decision to ensure the continued viability of the hospital. Because the actions by appellant were permissible under the corporate bylaws and done in good faith, there was no breach of contract between the appellant and its staff. The medical staff had no authority over any corporate decisions unless specifically granted that power in the corporate bylaws or under statute.
10. Hospital’s survival at stake, allowed unilateral change of bylaws
11. Notes 1 & 2: Is the tripartite division the best structure for efficient operation of hospital? In places with strong CPMD, it won’t be gone any time soon.
12. **Austin v. Mercy Hospital** bylaws are quasi-contract
13. Similar to St. Luke’s. Hosp made unilateral change to ICU privileges policy. Hosp wanted to professionalize its ICU staff; critical care specialists only. Bylaws required input from med staff before change could be made. Court enforced the bylaws against the hospital. Consistent with many, though not all states.
14. **Mateo v Fresno Hosp. 508** *quasi-legislative act supercedes bylaws*
15. Anesthesiologists’ practice of billing-based case selection sometimes failed to align particular anesthesiologists’ skills with the needs of particular cases. The board reviewed the practice and sought to terminate the practice. The court felt that this decision was within the board’s power, although the procedure by which the decision was implemented did not comply with the due process provisions of the hospital bylaws.
16. Important distinction: The court said this was a restructuring decision made by the board, which does not require strict *compliance with contractual due process. This is a quasi-legislative restructuring which did not involve the credentialing of individual physicians.* The fact that the hosp. was concerned with patient safety gave their decision added authority.
17. **St. John’s med-staff v. St. John Med-Center**: strong-contract view of medical bylaws
18. The med-staff bylaws were adopted and approved by the medical center. The bylaws contained an article stating that the bylaws were equally binding on both parties. Also, the bylaws provided a specific procedure for amendments (due process). Board unilaterally adopted new bylaws not approved by the med-staff.
19. The court held that the original bylaws were binding upon the medical center. Thus, any amendments to the bylaws should have been made in accordance with the due process procedure contained in the bylaws. The court held that the medical center breached the contract with the medical staff by ignoring procedure and unilateral amendments were void.
20. **Greisman v. Newcomb Hospital**: Pre-Darling; Right to procedural fairness
21. Hospital challenged a requirement that hospital consider plaintiff doctor's application for membership on the med-staff, although bylaws established that applicant must have graduated from AMA approved medical. Hospital contended that it was a private rather than a public hospital and that no legal ground existed for judicial interference with its refusal to consider plaintiff's application for membership.
22. The court held that hospital’s exclusion was arbitrary. The public interest and considerations of fairness and justness pointed unerringly away from the hospital's position.
23. Does he have standing to sue bylaws when they don’t yet apply to him?
24. Yes. The bylaws regulated the only hospital in town, which acts as a public utility, which is restricted from discrimination.
25. “Right to procedural fairness” often only inferred under special circumstances; public / patient interest, antirust, tortuous interference, for example.
26. **Nanavati v. Burdette Tomlin Memorial Hospital** court remands to hospital for hearing under bylaws
27. Cardiologist, only one in county, gets hosp privileges. Seeks to get EKG privileges.
28. He became disruptive when privileges not granted. This violated bylaws and the hosp sought termination
29. Bylaws not followed at termination proceedings.
30. Court remanded to the hospital to redo the proceedings in accordance with due process provisions of bylaws.
31. Other causes of action
    1. Civil rights: if excluded for nefarious causes
    2. Statutory defenses at the state level: “Due process” statutes
32. **Managed Care Contracts: Doc v MCO conflicts (523-27)**
33. No bylaws; contract instead. The K will control, it is very often dispositive.
34. ISSUE: is the nature of the MCO contract such that the court should bolster the provisions? Rarely, the answer is yes.
35. Public interest in not throwing doctor out of MCO which has natural monopoly in that region. Public utility analogy may arise. Patients do not have standing to bring suit.
36. Duty of fair dealing may be applied, duty of non-discrimination, common law duty of fairness.
37. Any willing provider state laws
38. MCO due process state requirements
39. Certain due process required to exclude doc from network
40. No-cause termination provisions
41. Docs want them; if for-cause only then the MCO would have to trump-up some dirt on your record to get rid of you
42. W/ no-cause MCO which is determined to get rid of you doesn’t have to hurt you. Does open door for abuse (Putnam case)
43. Contract of adhesion issues (severe power imbalance against monopoly MCO)
44. Potvin and Harper cases found public-interest in MCO – this is rare
45. **Potvin v MetLife p523** Common law right to fair procedures
46. After removal from insurance company's preferred provider lists, physician sued. Citing the common law right to fair procedure, doc alleged he should have been given reasonable notice and an opportunity to be heard before his removal.
47. The Supreme Court concluded that appellant alleged that among the adverse effects of removal from respondent's preferred provider lists were rejection by physician groups which were dependent upon credentialing by respondent and devastation of appellant's practice.
48. Proof of doc’s allegations could establish that, in terminating a physician's preferred provider status, respondent wielded power so substantial as to significantly impair an ordinary, competent physician's ability to practice medicine in a particular geographic area, thereby affecting an important, substantial economic interest.
49. Common law right to fair procedures. Doc waived it incontract with MCO
50. Ct found the agreement void to the extent it limited the important public policy of the common law right of fairness.
51. Note that insurers often have a virtual monopoly and if they choose to exclude a doctor they can ruin his career. (States have not gone the same way on this issue)
52. **Harper v. Healthsource New Hampshire** no-cause provision upheld but made reviewable
53. The physician contended that termination without cause provision in the agreement, or the termination in the case, was void as against public policy, that the HMO was a state actor required to afford him equal protection and due process,
54. The court stated that there was not an employee relationship, as the doc was barely an independent contractor, that the HMO’s contract validly included a no-cause termination clause enforceable against the doc, and that public policy requires that this termination be made available for independent review due to the public interest in the employment of doctors.

**VII. HEALTH CARE FRAUD AND ABUSE LAWS**

1. **CIVIL FALSE CLAIMS ACT,** This is legislation to prevent fraud by persons selling services to the government. Relevant in health care after Medicare/Medicaid became a major payer for health care.
2. Elements
3. Presented or caused to be presented a claim for payment or approval
4. Claim was false or fraudulent
5. Scienter: Defendant’s acts were undertaken “knowingly” with bad intent
6. [Damages to government] [\*\*Note: there is unsettled caselaw whether this is a required element]
7. Definition of “Knowingly” - Included: (a) actual knowledge; (b) deliberate ignorance of truth or falsity; or (c) reckless disregard of truth or falsity
8. **US v. George & Blanka Krizek**, (674 and 681).
9. This is the case of the reckless overbilling in mom & pop psych office. They were so careless with their billing, and were overbilling the gov’t, that it satisfied the scienter requirement.
10. Penalties- $5,500 to $11,000 per claim *plus* three times the amount of damages sustained by the government
11. Recent twist - Bringing FCA actions based on underlying violations of other legal provisions, including the Anti-Kickback Statue, the Stark Law medical necessity requirements, and quality of care requirements
12. **Mikes v. Straus**, p686
13. Employee of med-practice claimed that the negligent performance of a procedure billed to Mediare amounted to a false claim.
14. A cause of action based on an express false certification theory failed as the employee only challenged the quality of the procedure, not the decisions to order the procedure for patients. The employee failed to support her contention that the tests were not medically necessary and proffered no evidence that the providers had not personally furnished the tests as required by the Medicare reimbursement forms.
15. Acknowledging the viability of an implied certification theory for liability, the appellate court held that the claim did not succeed as the employee had only contended that the performance of test was qualitatively deficient.
16. Since the Medicare “medical necessity” provision did not expressly condition payment on compliance with its terms, the providers' certification on the Medicare forms were not legally false.
17. The worthless services claim failed as the employee did not show that the providers knew that their claim forms were false.
18. Qui Tam Actions: p699; private person can bring false claims suit in the name of the gov’t and can get a slice of the penalty.
19. **MEDICARE FRAUD AND ABUSE (ANTI-KICKBACK) STATUTE,** the anti-kickback statute prevents the use of certain types of inducements that might encourage overconsumption of health care services for which Medicare has to pay.
20. Purpose of statute**:**  prevent inducements that cause overutilization, prevent increases in fees (or kickbacks), and prevent undue financial influences on where patients go for care and the types of care they receive.
21. Basic structure of the statute**:**
22. It very broadly bans all behavior of a certain type (see general prohibition below).
23. Then, it provides for some regulatory “safe harbors” that are OK. To be safe, you have to fit *exactly* in a safe harbor.
24. If you don’t fit exactly in a safe harbor, it doesn’t necessary mean that what you are doing is *per se* illegal.
25. When you are doing something that does not fit into a safe harbor, the government will apply a purpose-based analysis to decide whether what you are doing is OK or not.
26. **General Prohibition*: This summarizes the statute on pages 702 -03 of Furrow***
27. Knowingly and willfully (not the same as False Claims Act—see below).
28. Pay or receive (or offer or solicit)
29. Any remuneration ( not just a bribe, but loans, free parking, discount on office space, free tickets, Includes any benefit, including a fee for services)
30. To induce someone to refer patients or to purchase, order or recommend
31. Any item or service that may be paid for under a federal health care program
32. Private right of action – Based on *qui tam* provisions of Civil False Claims Act (“FCA”)
33. **Key Legal Principles**
34. Intent standard: The statute may be violated if even *one* purpose of the remuneration is to induce referrals or purchases, even if there are other legitimate purposes as well.
35. Though some financial benefits may be too remote or *de minimis* to affect referral practices, threshold is low.
36. Giving a potential referral source the opportunity to earn a fee that exceeds the reasonable value of the services provided (or a reasonable return on an investment) is evidence that the payment is unlawful.
37. To be an inducement, the remuneration need only be *intended* to influence the customer’s judgment.
38. A violation may be found even if the arrangement doesn’t result in increased costs to health care programs.
39. The fact that an arrangement is common in the industry is not a defense.
40. **Statutory Exceptions and Safe Harbors**
41. Statutory Exceptions on pages 719 – 724.
42. Congress directed the Secretary of HHS to issue regulations defining “Safe Harbors”—i.e., practices that are deemed not to violate the Antikickback Statute.
43. Each safe harbor has specific criteria, but common requirements include; (i) signed written agreement; (ii) minimum one-year term; (iii) fair market value; (iv) compensation set in advance and not dependent on volume/value of referrals or other business between the parties
44. **Enforcement: Purposed-based analysis** (when something doesn’t fit into a safe harbor, yet potentially fits within the elements of the general prohibition). In determining whether to prosecute, the government looks at a variety of factors, including:
45. Potential for increased charges or costs to payers, especially the government?
46. Potential for encouraging overutilization of items/services?
47. Potential for harm to beneficiaries?
48. Legitimate business purpose for entering into the arrangement?
49. Intent of the parties?
50. Penalties
51. Criminal felony
52. Up to 5 years in prison and $25,000 in fine
53. Exclusion from federal health care programs
54. Debarment from government contracting
55. Civil and administrative penalties
56. Exclusion or debarment in an administrative proceeding
57. Civil Monetary Penalties (CMP) of $50,000 per violation, plus not more than three times the total amount of remuneration
58. CMP for inducements given to beneficiaries
59. Exclusion from federal programs (this could wreck a practice)
60. Continuum of interpretation (Greber - harsh > Starks > Hanlester - lax)
61. **Greber** p707: Payments, even for legitimate services, made with **any** intent to induce referrals are barred.
62. Defendant argued that payments made to a physician for professional services could not be the basis of Medicare fraud. Defendant insisted that absent a showing that the **only** purpose behind the fee was to induce future services, compensating for services actually rendered could not be a violation of.
63. The court concluded that if the payments were intended to induce the physician to use his organization's services, the statute was violated, even if the payments were also intended to compensate for professional services. The court held that materiality was an essential element and further held that the record contained enough evidence to support the district judge's ruling that the certifications to Medicare were material.
64. **Starks** p712-16.
65. Defendants, convicted in a federal district court under anti-kickback, appealed alleging that they had to have known that their medical referrals arrangement was illegal in order to be convicted. The court held that willfulness element of law simply means acting with the general knowledge that those actions are in violation of statute, proper understanding of which is presumed when the statute is not highly technical or complex.
66. **Hanlester** v. Shalala, held that a violation cannot be found unless the defendant; (1) knew that the law prohibited giving or receiving remuneration for referrals; and (2) acted with the specific intent to violate the law –
67. But Hanlester analysis has not been accepted by all courts and Hanlester has been called into question in other circuits.
68. **PHYSICIAN SELF-REFERRAL LAW (STARK LAW),** 730-43—seeks to curb practices that could lead to overutilization of Medicare-paid services, by prohibiting transactions in which doctors encourage patients to do business with labs or other service providers in which the doctor has a financial interest.
69. Section 1877 of the Social Security Act (the Act) (42 U.S.C. 1395nn), also known as the physician self-referral law and commonly referred to as the "Stark Law":
70. Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.
71. Prohibits the entity from filing claims to Medicare (or billing another individual, entity, or third party payer) for those referred services.
72. Establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.
73. Key differences in approach between Stark and Anti-kickback**:**
74. Stark has no scienter requirement. Intent does not matter. If a doctor makes a prohibited referral, a violation has occurred, regardless of intent.
75. Stark has only civil money penalties, no criminal penalties.
76. Unlike Anti-Kickback, Stark applies only to physicians and prohibits remuneration only for specific types of health care items/services
77. Stark exceptions do not work the way Anti-kickback safe harbors work. If conduct does not fit into a Stark exception then it is illegal, period.
78. If conduct does not fit exactly into an Anti-kickback safe-harbor, that does not mean it is necessarily illegal. You analyze the conduct under the general Anti-kickback statute and look at the purpose and intent of the conduct.
79. Whenever Stark applies, the Anti-kickback statute also applies. Some lawyers recommend you start with the Stark analysis. If you have a Stark problem, you don’t need to bother to do Anti-kickback analysis, since the conduct is already illegal under Stark.
80. If the Stark analysis suggests that the conduct is OK under Stark, then you go on and do the Anti-kickback analysis, to see if the conduct is OK there too.
81. Penalties**.**
82. Civil penalties may be imposed for violation of the Stark law. Penalties include
83. denial of payment,
84. refunds of amounts collected in violation of the law,
85. up to $15,000 in civil monetary penalties for each claim submitted in violation of the law,
86. up to $100,000 in civil monetary penalties for each arrangement or "scheme" that violates the law,
87. a civil monetary penalty of three times the amount claimed, and
88. exclusion from participation in the Medicare program or other government health programs.
89. Financial RelationshipDefined as one of the following:
90. An Ownership or Investment Interest in the Entity. An equity, debt, or similar ownership or investment interest in an entity that provides DHS.
91. A Compensation Arrangement. Any arrangement involving remuneration between a physician (or immediate family member) and an entity that provides DHS.
92. An Indirect Financial Relationship: a relationship between an entity with which the physician has an ownership or compensation arrangement and another entity which furnishes DHS. The doc must have actual knowledge of the relationship or act in reckless disregard or deliberate ignorance of the existence of the relationship.
93. ReferralDefined as follows:
94. A referral includes a request by a physician for an item or service for which payment may be made under Medicare Part B, including the request for a consultation with another physician and the request or establishment of a plan of care by a physician that includes a DHS.
95. Excluded from the definition are requests by pathologists, radiologists, and radiation oncologists for services furnished as the result of a consultation by another physician.
96. **Stark Exceptions.** MUST FIT EXACTLY
97. Exceptions to Both Ownership and Compensation Arrangements.
98. Physicians' Services, In-Office Ancillary Services, Prepaid Plans, Academic Medical Centers, Implants in ASC, EPO furnished in or by ESRD facility, Preventative Screening Tests, Eyeglasses and Contacts following Cataract Surgery, Intra-family referrals
99. Exceptions to Ownership Arrangements.
100. Ownership in Publicly Traded Securities, and Mutual Funds, and Hospitals
101. Rural Providers
102. Exceptions to Compensation Arrangements.
103. Rental of Office Space and Equipment, Bona Fide Employment, Personal Services Arrangements, Remuneration Unrelated to DHS, Physician Recruitment, Group Practice, Arrangements with a Hospital, Physician Payments, Isolated Transactions, Fair Market Value Compensation, Non-Monetary Compensation, Medical Staff Incidental Benefits, Risk Sharing Arrangements, Compliance Training, Indirect Compensation Arrangements, Charitable Donations by Physicians, Referral Services, Obstetrical Malpractice Insurance, Professional Courtesy, Retention Payments in Underserved Areas, Community-Wide Health Information Systems