BACK TO BASICS:
Basics of Hospital Law

California Society for Healthcare Attorneys

Julie A. Simer, Esq.
Buchalter Nemer
A Professional Corporation
18400 Von Karman Avenue, Suite 800 | Irvine, CA 92612-0514
Direct Dial: (949) 224-6259 | Direct Fax: (949) 224-6481
Email: jsimer@buchalter.com | www.buchalter.com

TABLE OF CONTENTS

Page

I. REFERENCE 1
- A. *Statutes and Regulations* 1
- B. *Websites:* 2
- C. *General Reference* 2
- D. *Trade Organizations* 2
- E. *Alerts:* 2

II. HOSPITAL STRUCTURE 3
- A. *Nonprofit Hospitals* 3
- B. *For-Profit Hospitals.* 5
- C. *Local Health Care District Hospitals.* 5

III. HOSPITAL GOVERNANCE 5
- A. *Role of the Board of Directors.* 5
- B. *Conflict of Interest.* 5
- C. *Corporate Compliance.* 6

IV. THE MEDICAL STAFF 7
- A. *Structure* 7
- B. *Physicians.* 9
- C. *Allied Health Professionals.* 12

V. HOSPITAL LICENSING 12
- A. *Oversight* 12
- B. *Seismic Retrofit* 13

VI. ACCREDITATION 13
- A. *The Joint Commission* 13

VII. GETTING PAID 14
- A. *Medicare* 14
- B. *Medi-Cal* 15
- C. *Private Insurance* 15
- D. *Knox-Keene Health Care Service Plans.* 16
- E. *Managed Care Contracting Notes.* 16
- F. *Workers' Compensation.* 18
- G. *Miscellaneous.* 18
- H. *Hospital Liens* 19

VIII. FRAUD AND ABUSE STATUTES 19
- A. *The Anti-Kickback Statute (40 U.S.C. § 1320a-7b(b)) and Safe Harbors* 19
- B. *The Stark Law (42 U.S.C. § 1320a-7b(b)) and Exceptions* 20
- C. *False Claims Act (31 U.S.C. § 3729-3733).* 21
- D. *Criminal False Claims Act (18 U.S.C. § 287).* 21

E. *Exclusion Statute (42 U.S.C. § 1320a-7).* 21
F. *Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a).* 21
G. *Spier Law.* 21
H. *Other Tools.* 21

IX. ANTITRUST LAW 21
A. *The Sherman Act* 21
B. *Mergers and Acquisitions.* 22
C. *Managed Care.* 23

X. DATA PRIVACY AND SECURITY 23
A. *Health Insurance Portability and Accountability Act ("HIPAA").* 23
B. *Health Information Technology for Economic Clinical Health Act (HITECH)* 25
C. *California Privacy Statutes* 25
D. *Social Media* 26

XI. EMTALA 26
A. *Emergency Medical Treatment and Labor Act.* 26
B. *On-call Issues* 27

XII. PPACA AND ACCOUNTABLE CARE ORGANIZATIONS 27
A. *Medicare Shared Savings Program* 27

XIII. PPACA CHANGES TO MEDICARE FRAUD ENFORCEMENT 28
A. *Qui Tam Actions.* 28
B. *Health Care Fraud Prevention and Enforcement Action Team (HEAT).* 28
C. *False Claims Act.* 28
D. *Self-Reporting.* 29
E. *Expansion of Recovery Audit Contractor (RAC) Programs.* 29

XIV. PPACA MEASURES FOR QUALITY IMPROVEMENT 29
A. *Quality Improvement Initiatives.* 29

XV. OTHER LAWS IMPACTING HEALTH CARE 30
A. *Intellectual Property.* 30
B. *Human Resources/Labor.* 30
C. *Hazardous Wastes.* 30
D. *Non-Discrimination* 30

I. REFERENCE

A. Statutes and Regulations

1. **Corporate Practice of Medicine** (See Business and Professions Code § 2032, § 2052, and § 2400.)

2. **Health Care Reform**

    a. Patient Protection and Affordable Care Act (PL 111-148) March 23, 2010 amended by the Health Care and Education Reconciliation Act of 2010 (PL 111-152) March 30, 2010.

3. **Hospital Licensing**

    a. Health & Safety Code § 1250, *et seq.*
    b. Title 22, California Code of Regulations

4. **Knox-Keene Act**

    a. Health & Safety Code § 1300, *et seq.*

5. **Medi-Cal and other State Payment Programs**

    a. Welfare and Institutions Code

6. **Medicare**

    a. 42 U.S.C.
    b. 42 Code of Federal Regulations

7. **Medical Staff**

    a. Business & Professions Code § 805, *et seq.*

8. **Privacy and Security**

    a. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) – Public Law 104-191.
    b. Health Information Technology for Economic and Clinical Health Act (HITECH) enacted as part of the American Recovery and Reinvestment Act (Public Law 111-5). 42 U.S.C. § 17932
    c. Civil Code § 56.36
    d. Health and Safety Code § 1280.15
    e. Civil Code § 1798.82

9. **Peer Review**

   a. Evidence Code § 1157 – protection from disclosure

10. **Provider Licensing**

   a. Business & Professions Code

B. Websites:

1. Center for Medicare & Medicaid Services (CMS) – www.cms.gov/
2. Department of Health Care Services – www.dhcs.ca.gov/Pages/default.aspx
3. Dept. of Insurance – www.insurance.ca.gov/
4. DMHC – www.hmohelp.ca.gov/providers/default.aspx
5. Joint Commission – www.jcaho.org
6. Office of Inspector General (OIG) – www.oig.hhs.gov

C. General Reference

1. <u>Consent Manual</u>, California Hospital Association (CHA)
2. <u>California Physician's Legal Handbook</u>, California Medical Association
3. <u>Comprehensive Accreditation Manual for Hospitals</u>, Joint Commission
4. BNA Health Law Business Reporter and Health Law Business Library
5. CCH Health Care CD
6. Modern Healthcare
7. Wall Street Journal

D. Trade Organizations

1. American Health Lawyers Association (AHLA), www.healthlawyers.org
2. Health Care Financial Management Association (HFMA), www.hfma.org
3. California Hospital Association (CHA), www.calhospital.org
4. California Medical Association (CMA), www.cmanet.org
5. American Bar Association, health law section (ABA), www.americanbar.org
6. Hospital Association of Southern California (HASC), www.hasc.org
7. County Bar Associations

E. Alerts:

1. State Bar Business Law Section: Health Law Committee List Serve
2. Health Law 360, www.law360.com/health
3. Find Law, http://newsletters.findlaw.com
4. Lexology, www.lexology.com

5. Law Firm e-newsletters and RSS feeds
6. Kaiser Health News, www.kaiserhealthnews.org

II. HOSPITAL STRUCTURE

A. Nonprofit Hospitals

1. Usually formed as "public benefit corporations" or "religious organizations." (Corporations Code § 5000, *et seq.*).

2. "Tax exempt organizations" under federal tax law (501(c)(3) and California law (California Revenue and Taxation Code § 23701d).

3. May receive tax-deductible contributions and are not required to pay property taxes in California on property used for exempt purposes.

4. California law (Health and Safety Code § 127340) requires a community needs assessment, adoption of a community benefits plan and submission of an annual reporting to Office of Statewide Health Planning and Development (OSHPD).

5. Recent Cases

   a. Provena Covenant Med. Ctr. v. Illinois Department of Revenue, 2010 Ill. LEXIS 289 (Mar. 18, 2010). The hospital did not qualify for the charitable under Ill. Law, because the state statute specifically requires that the subject property be "actually and exclusively used for charitable or beneficial purposes and not leased or otherwise used with a view to profit."
   b. Covenant Healthcare System, Inc. v. City of Wauwatosa (Jul. 22, 2011) — A Wisconsin statute provides a property tax exemption for nonprofit hospitals. Wisconsin Supreme Court held that the outpatient clinic was used for the primary purposes of a hospital and therefore qualified as tax-exempt property.
   c. In, Dialysis Clinic, Inc. v. Levin, Supreme Court of Ohio, (Oct. 26, 2010), the state board of tax appeals properly denied a dialysis clinic a "charitable use" tax exemption for one of the properties on which the clinic operates, because the clinic provides no free or charitable service at the subject property.

6. Must meet IRS regulations and comply with anti-kickback and self-referral laws. Subject to scrutiny by the Internal Revenue Service (Exempt Organizations Division).

7. Private Inurement. Assets of the tax-exempt organization may not be used for private purposes. Violations of the use restrictions can lead to loss of the tax-exemption on the interest paid on the bonds to private bondholders. Subject to scrutiny: Medical Directorships, Leases to Physicians, Clinical Trials

8. Private Benefit. Primary use must benefit the organization's tax-exempt purposes.

9. Intermediate Sanctions. The IRS may impose "intermediate sanctions" for violations of IRS laws and regulations, "excise taxes" on the individuals or entities improperly benefitted (including the nonprofit organization's insiders involved in approving such transactions). Penalties may be up to 25% of the amount of the excess benefit for the recipient and up to $10,000 for the insiders approving the transaction. If the excess benefit and the penalties are not repaid as required by the law, the excise tax can be as high as 200% of the excess benefit. See 26 C.F.R. § 53.4958.1.

10. Executive and board compensation and transactions with physicians are scrutinized.

11. May not participate in political campaigns.

12. "Profits" must be re-invested in the nonprofit organization, not distributed to members.

13. Capital needs are met through:

   a. Positive operating margins
   b. Tax-deductible contributions
   c. Borrowing (often, tax-exempt bonds issued through local or state agencies)

14. Must comply with state licensing requirements.

15. The California Attorney General's Charitable Trust Division oversees California's nonprofit hospitals. Charitable trust law applies to the assets of nonprofit organizations in California.

16. State and federal laws applicable to for-profit organizations also apply to nonprofit organizations. Under Corporations Code §§ 5914-5925, nonprofit hospitals are required to provide written notice to, and to obtain the written consent of, the Attorney General prior to entering into any agreement or transaction to sell, transfer, lease, or exchange a material amount of the assets of the nonprofit to any for-profit corporation or mutual benefit corporation.

17. Under the Patient Protection and Affordable Care Act (PPACA), Federal requirements for tax exempt organizations:

a. Community health needs assessment
b. Financial assistance policy
c. Charges for those qualified under financial assistance policy limited to the amounts generally charged to insured patients
d. Annual reporting requirements (Form 990)

18. Penalties:

a. Loss of Exemption
b. Excise Tax of $50,000 per year

B. For-Profit Hospitals.

1. No charitable obligations; though, like nonprofit hospitals, for-profit hospitals often take indigent patients in their emergency rooms as required by the Emergency Medical Treatment and Active Labor Act ("EMTALA").

C. Local Health Care District Hospitals.

1. Local governmental agency run hospitals that are often called "District Hospitals". (See Health and Safety Code § 32000, *et seq.*) A number of District Hospitals have transferred their facilities or operations to nonprofit hospital organizations pursuant to Health and Safety Code § 32121(p).

III. HOSPITAL GOVERNANCE

A. Role of the Board of Directors.

1. A Board of Directors governs most hospitals. Larger organizations may have a parent "holding" company and subsidiary hospital corporations of which the parent is either the sole shareholder (or sole member under the nonprofit laws). Alternatively, the organization has a single corporation structure with local "advisory" boards at each of the hospitals.

2. Corporations operate pursuant to their bylaws. Administrative duties and operations are conducted by an executive team of a CEO, CFO, and COO. The general counsel may be part of the executive team.

B. Conflict of Interest.

1. The board of directors, its executives and other employees have fiduciary responsibilities to the organization:

a. Good Faith: the duty to act in good faith and in the best interests of the entity.
b. Loyalty: May not appropriate or divert to others any opportunity in connection with a transaction in which it is known, or could be reasonably anticipated, that the entity is or is likely to be interested and shall not enter into transactions or relationships that would compromise his or her ability to provide good faith direction to the entity.
c. Confidentiality: Must refrain from using or disclosing confidential information outside the scope of the person's duties with respect to the entity.
d. Avoidance of Improper Influence. May not accept more than nominal gift or benefit from any person or entity doing business or seeking to do business with the entity. Transactions involving interested physician leaders, administrative executives, and governing board members may be approved by a nonprofit organization, if there are findings that:

   (i) The transaction is fair and reasonable as to the entity.
   (ii) The entity could not have obtained a more advantageous arrangement with reasonable effort under the circumstances.

C. Corporate Compliance.

1. In re Caremark International Inc. Derivative Litigation, 698 A.2d. 959 (Del. Ch. 1996). Although the board in the Caremark case did not breach its fiduciary duties, the court stated:

   a. [A] director's obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the Board concludes is adequate, exists, and that failure to do so under some circumstances, may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards.

2. The OIG and HHS, through its Compliance Program Guidance for Hospitals in 1998 and Supplemental Compliance Program Guidance for Hospitals in 2005, strongly encouraged hospitals to adopt an effective compliance program which includes:

   a. A Code of Conduct
   b. Regular Review of Compliance Program Effectiveness
   c. Designation of a Compliance Officer (other than the general counsel) and a Compliance Committee

d. Development of Compliance Policies and Procedures, including Standards of Conduct
e. Developing Open Lines of Communication
f. Appropriate Training and Education
g. Internal Monitoring and Auditing
h. Response to Detected Deficiencies
i. Enforcement of Disciplinary Standards
j. Self-Reporting

3. The governing authority must be knowledgeable about the content and operations of the compliance program and exercise reasonable oversight over it.

4. The general counsel and outside lawyers play a critical role assisting the board to exercise its oversight obligation. The role of the general counsel is to act as a counselor to help the board understand the relevant laws and regulations so that the board may analyze the associated business risks. The general counsel is encouraged to "assist in the design and maintenance of the corporation's procedures for promoting legal compliance."

5. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 made it mandatory for hospitals receiving Medicare funds to have a compliance program.

IV. THE MEDICAL STAFF

A. Structure

1. A medical staff is an organization of physicians and other limited licensed practitioners authorized to provide clinical services in a hospital. The concept of the medical staff originated in 1917 when the American College of Surgeons included in its original accreditation standards the requirement that physicians who wanted to practice in a hospital must be organized as a separate and distinct medical staff. The medical staff must establish the rules, regulations and policies for the professional work of the hospital.

2. In California, a hospital governing body must adopt bylaws which provide for the formal organization of the medical staff with appropriate officers and bylaws. 22 CCR § 7701(a)(1) (D). A medical staff is self-governing with respect to the professional work that is performed in the hospital. Health & Safety Code § 32128(a)(3); Bus. & Prof. Code § 2282(c). It is responsible to the hospital governing body for the adequacy and quality of the care rendered to patients. 22 CCR § 70703(a).

3. Under the Joint Commission accreditation standards, the medical staff is the component of a hospital that "has the primary responsibility for the

quality of care in the hospital." In an accredited hospital, the organized medical staff is responsible to the hospital governing body for the quality of in-hospital medical care; it evaluates the qualifications of applicants and holders of staff privileges; it recommends appointment, reappointment, curtailment and exclusion from staff privileges; it provides peer group methods for reviewing basic medical, surgical and obstetrical functions. Matchett v. Superior Court, 40 Cal.App.3d 623, 628 (1974).

4. The work of the medical staff is performed in the following manner:

> The medical staff acts primarily through a number of peer review committees, which, along with other responsibilities, assess the performance of physicians currently on staff, review the need for and results of each surgery performed in the hospital, and the control of in-hospital infections. (Cal. Code Regs., tit. 22, § 70703, subds. (b) & (d).) If a peer review committee recommends that the privileges of the physician be restricted or revoked because of the manner in which he or she exercised those privileges, a series of procedural mechanisms kick into play-all governed by state law. (Bus. & Prof. Code, §§ 809-809.8; Cal. Code Regs., tit. 22, § 70703, subd. (b).)

Unnamed Physician v. Board of Trustees of Saint Agnes Medical Center, 93 Cal.App.4th 607, 616 (2001).

5. Medical staffs have their own bylaws subject to the approval of both the medical staff and the hospital's board of directors. Medical staff bylaws in California are often based upon the California Medical Association's ("CMA") Model Medical Staff Bylaws. Various other committees work with and report to the Medical Executive Committee.

6. The chief officer of the medical staff, elected by the general medical staff, is referred to as the President of the Medical Staff or the Chief of Staff. Membership on a medical staff is restricted to "physicians and surgeons and other licensed practitioners competent in their respective fields and worthy in professional ethics". (See Business and Professions Code § 2282.)

7. The rights of medical staff "self governance" include:

a. Establishing rules for medical staff membership and privileges and enforcing those criteria and standards.
b. Selecting and removing medical staff officers.
c. Assessing dues and using them for appropriate medical staff purposes.

d. Ability to retain independent legal counsel at medical staff expense.
e. Initiating, developing, adopting and amending medical staff bylaws, rules and regulations subject to the reasonable approval of the hospital governing board.
f. Initiating legal actions against a hospital for obstructing or about to obstruct those rights. (See Business and Professions Code § 2282.5.)

B. Physicians.

1. Apply to a hospital's medical staff for membership and clinical privileges.

2. California has a prohibition against the corporate practice of medicine. (See Business and Professions Code § 2032, § 2052, and § 2400.) California law generally provides that only persons (as opposed to corporations and the like) can practice medicine in the state. There are limited exceptions to the prohibition (for example, it is permissible for professional corporations owned by licensed physicians to employ physicians). A key factor in determining whether the prohibition applies is whether the licensed physician retains control of the patient relationship and the care to be provided to a patient. (See California Assn. of Dispensing Opticians v. Pearle Vision Center, Inc., 143 Cal.App.3d 419 (1983).

a. Hospitals may enter into contractual relationships with physicians for a variety of clinical-related administrative services. For example, Title 22 requires physician oversight for various hospital services. These positions are often referred to as "medical directors".
b. All relationships with referring physicians that are financial in nature must meet anti-kickback statutes and regulations.

3. Credentialing is the important process of assessing and evaluating the qualifications of physicians to practice their profession in a hospital. Medical staffs and hospitals take this important role very seriously. While medical staffs do the actual review of physician qualifications and report their recommendations to the hospital's board of directors, the board of directors has the final authority to determine which physicians are granted membership and clinical privileges. (See Health and Safety Code § 1250 and § 1275, and Title 22 California Code of Regulations, § 70703.)

a. Failure of a hospital to adequately credential physicians or discipline physicians on a hospital's medical staff can render the hospital liable for injuries to a patient caused by that physician's negligence. Elam v. College Park Hospital, 132 Cal.App.3rd 332, 183 Cal. Rptr. 156 (1982).

4. Physicians who are not granted membership, privileges or who are disciplined for a "medical disciplinary reason" must be reported by the hospital to the Medical Board of California. (See Business and Professions Code § 805.) Additionally, a second report must be sent to the National Practitioners Data Bank in compliance with the Federal Health Care Quality Improvement Act of 1986, 42 U.S.C. 11101, *et seq.*

a. Failure to make the required reports subject the respective hospital's administrator and medical staff officer to significant fines and penalties.
b. Fines can exceed $50,000 per violation; up to $100,000 for willful failure to file. (See Business and Professions Code § 805.)
c. Note that with regard to claims of professional malpractice involving physicians, insurers are required to make reports to the Medical Board of California of (i) settlements in excess of $30,000, and (ii) arbitration awards and civil judgments of any amount. The report is required even if the party to the settlement is a corporation, medical group, partnership or other corporate entity in which a physician has an ownership interest or that employs or contracts with a physician. (See California Business and Professions Code § 801(b).)
d. Both the 805 Report and the Data Bank Report must be filed within the time established by the law. The time requirements are different.

5. Fair Procedure Rights. Because "805 Reports" and Data Bank Reports may be a death knell to a physician's practice and livelihood, fair procedure rights are afforded to a physician before an adverse action can be taken that would lead to such a report. California's courts have long recognized that physicians have a substantial property interest in being allowed to practice at a hospital. A body of case law has been developed holding that a hospital cannot arbitrarily deny a physician's request to practice at a hospital. Adverse Actions include:

a. A physician's application for staff privileges or membership is denied or rejected for a medical disciplinary cause or reason.
b. A physician's membership, staff privileges, or employment is terminated or revoked for a medical disciplinary cause or reason.

c. Restrictions are imposed or voluntarily accepted on staff privileges, membership, or employment for a cumulative total of thirty days or more for any 12-month period, for a medical disciplinary cause or reason.

d. Other requirements for reporting also apply. It is important to read both the California and federal statutes and regulations to determine when both reports are required to be made.

6. Fair procedure rights involve a fair hearing process before the Judicial Review Committee, a committee of physicians appointed by a medical staff to review the matter. A physician is also entitled to a notice of charges and a reasonable opportunity to respond to those charges. The hearing rights are outlined and detailed in the medical staff's bylaws and reflect the requirements imposed by federal and state law. (See Business and Professions Code § 809, *et seq.*)

a. California's courts are available to physicians to review the standards applied in any given case to assure they are not "substantively irrational or otherwise unreasonably susceptible to arbitrary or discriminatory application." Miller v. Eisenhower Medical Center, 27 Cal.3d 614, 626-627, 166 Cal. Rptr. 826 (1980).

b. The Judicial Review Committee may not consist of medical staff members who have previously participated in decisions regarding the charged physician or those members who may be biased. The hearings are usually conducted before a hearing officer, often an attorney, with a court reporter present. The Judicial Review Committee hears from both the medical staff as well as the affected physician. Parties have cross-examination rights. Furthermore, the parties may introduce witnesses and documents to support their position. The Judicial Review Committee renders a written decision on the matter. Either party may appeal the decision to the hospital's board of directors.

c. Once the hearing process is complete, including any rights of appeal to the hospital's board of directors, the disappointed party may appeal the matter to the Superior Court.

d. The Health Care Quality Improvement Act of 1986 provides immunity to peer review committees and hospitals that take professional review actions from claims for damages related to their actions provided they act in a reasonable belief that the action was in furtherance of health care and they complied with procedural safeguards described in the Act.

7. Exclusive Arrangements.

a. Hospitals generally operate their medicals staffs on an "open staff" basis, meaning they will grant privileges to any physician who applies who meets the medical and professional qualifications. Some services have traditionally been operated on an "exclusive staffing" or "closed staff" basis. This means that a hospital will turn away otherwise qualified professionals if they are not part of the group that has been selected to staff the service. Centeno v. Roseville Community Hospital, 107 Cal. App. 3d 62, 76, 167 (1979); Mateo-Woodburn v. Fresno Community Hospital & Medical Center, 221 Cal. App. 3d 1169, 1184 (1990).

b. In 1983, the Medi-Cal Selective Provider contracting law forbade exclusive arrangements for contracting hospitals except in radiology, pathology, and anesthesiology. Until recently, this was completely ignored. State regulators have now indicated a willingness to enforce these regulations. (See Welfare and Institutions Code § 14087.28.)

C. Allied Health Professionals.

1. A medical staff is usually also responsible for credentialing and reviewing allied health professionals who may be granted privileges. The members of the allied health professional staff are the non-medical staff members who are not employed by or otherwise contracted with the hospital to provide services.

V. HOSPITAL LICENSING

A. Oversight

1. Health care facilities in California are licensed, regulated, inspected, and/or certified by a number of public and private agencies at the state and federal levels, including the California Department of Public Health (CDPH) and CMS. These agencies have separate – yet sometimes overlapping – jurisdictions

2. Hospitals also need specialized licenses and permits for particular services that are offered including pharmacy, radiology, and laboratory.

3. Most hospital services are operated under the hospital's license including all outpatient services. However, some free standing urgent care centers or surgi-centers that are hospital "sponsored" are separately licensed or operated under the law which allows physicians to provide such services in their offices.

4. “Outpatient Settings” where anesthesia is used (other than local or spinal blocks) must either be licensed, certified by Medicare or accredited by one of the organizations approved by the Medical Board of California to accredit outpatient settings. In order to qualify for accreditation, they must meet certain standards, including having an emergency plan and transfer agreement with a local hospital and credential and continuously evaluate their physicians. (See Health and Safety Code § 1248.15.)

5. Hospital license inspections come in two varieties: (i) as a part of the Joint Commission’s surveys (which now occur only once every three years for fully accredited hospitals); and (ii) in response to complaints or sentinel events (those surveys are unannounced and guaranteed to ruin even the most organized hospital’s day).

B. Seismic Retrofit

1. In 1994, a few months after the Northridge earthquake, California enacted SB 1953 requiring all California hospitals to meet sweeping new earthquake-compliance standards. Hospitals must determine which buildings are at risk of collapse during a major earthquake (with a magnitude of 7 or greater) and therefore must be seismically retrofitted to remain standing during and after a temblor by 2013. By 2030, they must be seismically retrofit to be able to remain operational immediately following an earthquake.

2. According to the California Hospital Association, 82% of California’s community hospitals and hospital buildings report that they will be compliant with the state’s seismic deadline requirements by 2015. The cost of making these seismic improvements ranges from $45 billion to $110 billion without financing costs, according to a 2007 study by the Rand Corp.

VI. ACCREDITATION

A. The Joint Commission

1. The California legislature enacted SB 1953 initiating a voluntary process whereby hospitals are surveyed to determine if they meet comprehensive standards created by the Joint Commission (JCAHO). JCAHO surveys are all-consuming for hospitals.

2. Facilities that are accredited by JCAHO qualify for Medicare payments, subject only to periodic Medicare validation surveys, which may be requested when a problem is suspected such as a violation of the federal anti-dumping laws. “Validation” surveys are unannounced and often focus initially on compliance with several standards, such as emergency services, medical staff, and administration. Non-compliance with standards can lead to threatened loss of Medicare funding.

3. Standards that are surveyed are divided into the following areas: Provision of Care, Leadership, Management of Environment of Care, Management of Human Resources, Management of Information and Medical Staff.

4. JCAHO continues to try to move away from paper compliance towards a meaningful assessment of the quality of care. JCAHO now asks about compliance over time rather than on the day of survey only. This encourages continual compliance, not just a spiffing up for the sake of the surveyors. Recent emphasis has been on patient safety improvements (establishing national "patient safety goals") and failure event modality analysis (a process for identifying and correcting potential failures before they occur). For example, JCAHO established new standards to banish "dangerous abbreviations" in medical records.

5. Beginning in 2006, JCAHO began conducting all accreditation surveys on an unannounced basis. JCAHO has also adopted a tracer methodology whereby JCAHO surveyor traces select individual patient files and examines all aspects of care provided to the patient.

VII. GETTING PAID

A. Medicare

1. Medicare is a federal program primarily for patients over the age of 65 and permanently disabled. In addition, Medicare has a special program for people of all ages who have end-stage renal disease. Medicare is a major source of funding for most hospitals. Payment for inpatient, non-psychiatric, non-children's hospital services is made under the Prospective Payment System ("PPS"), which is based upon diagnosis related groups (DRG), a hospital classification system that groups patients by common characteristics requiring treatment. DRGs are assigned by a "grouper" program based on ICD (International Classification of Diseases) diagnoses, procedures, age, sex, discharge status, and the presence of complications or comorbidities.

2. Physicians have a completely different incentive system when they are paid on a fee-for-service basis by Medicare. Payments are set using the Resource Based Relative Value System ("RBRVS") that bases reimbursement for physicians upon a theoretical analysis of what it costs to provide the service. Physicians may accept assignment from Medicare, which limits them to Medicare set fees. Physicians can opt out of Medicare, but this applies to all patients for an extended time.

3. Medicare's Ambulatory Payment Classifications ("APC") is an outpatient facility outpatient services for the Medicare program. APCs are an outpatient prospective payment system applicable only to hospitals.

Physicians are reimbursed via other methodologies for payment in the United States, such as Current Procedural Terminology (CPT) codes. APC payments are made to hospitals when the Medicare outpatient is discharged from the emergency department or clinic or is transferred to another hospital (or other facility) which is not affiliated with the initial hospital where the patient received outpatient services. Although APCs began through the federal system of Medicare, they have also been considered for adoption by state programs, such as Medicaid, and other third-party private health insurers. If the patient is admitted from a hospital clinic or emergency department, then there is no APC payment, and Medicare will pay the hospital under DRG methodology

4. Medicare Advantage Plans, sometimes called "Part C" or "MA Plans," are offered by private companies approved by Medicare. The MA plan provides all Part A (Hospital Insurance) and Part B (Medical Insurance) coverage. Medicare Advantage Plans may offer extra coverage, such as vision, hearing, dental, and/or health and wellness programs. Most include Medicare prescription drug coverage (Part D). Each Medicare Advantage Plan can charge different out-of-pocket costs and have different rules for how enrollees get services.

B. Medi-Cal

1. Medi-Cal, California's version of the Medicaid program, is a federal health care benefits program for indigent patients. Hospitals that treat very large numbers of Medi-Cal patients can receive disproportionate share hospital ("DSH") funds. These funds are designed to allow disproportionate share hospitals to "catch up" from the low reimbursement they receive from Medi-Cal.

C. Private Insurance

1. Traditionally insurance was indemnity insurance that paid providers on a fee-for-service basis for whatever services the providers deemed necessary. Early attempts to control insurance expenditures began to require demonstrations of "medical necessity." Audits were also used to determine whether services were rendered. Onerous paperwork documentation requirements were imposed before bills would be paid.

2. Insurers have been able to provide options for "preferred provider" panels and "exclusive provider" panels.

    a. The "preferred provider" option requires subscribers who use providers who are not on the "preferred provider" list to pay substantially more.

b. The "exclusive provider" option limits subscribers to using providers who are on the "exclusive provider" list, except in emergencies.

c. These "preferred provider" and "exclusive provider" options have become very popular.

d. Many panels started with many doctors and hospitals listed; insurers made efforts to limit participation in order to eliminate providers who are not cost-efficient and to provide incentives to reduce price through promises of increased volume. Usually, terminations are accomplished by invoking clauses in the agreements that allow termination of providers "without cause" upon a short notice period. Potvin v. Metropolitan Life Insurance Company, 22 Cal. 4th 1060, 95 Cal. Rptr. 2d 497 (2000) suggests that the third party payers are not free to terminate "without cause" and may need to offer hearings and valid reasons before depriving physicians of economically valuable contracts.

e. Hospitals and physicians often sign contracts promising deep discounts in their usual fees -- contractual allowances that they promise they will not try to recover from patients.

3. Insurers have more interest in reviewing the services provided by the providers on the panels. Usually, they rely on hospitals to undertake quality improvement review and credentialing; hence the popularity of insurance requirements that a physician be an active staff member of a particular hospital's medical staff in order to qualify for inclusion in the preferred provider or exclusive provider panel.

D. Knox-Keene Health Care Service Plans.

1. Knox-Keene Health Care Service Plans pay capitation payments in exchange for promises to provide all the covered services. Knox-Keene plans are regulated by the California Department of Managed Health Care, which requires companies to meet stringent standards on financial responsibility and reserves, as well as which services must be offered and programs implemented to assure quality.

2. The Knox-Keene Health Care Service Plans have gained in popularity, as employers try to reduce health care costs. They dominate some markets in California and are rapidly expanding in others.

E. Managed Care Contracting Notes.

1. Providers need to be extremely diligent and wary of managed care payment arrangements. Mistakes can be disastrous. For example, if a hospital

contracts for per diem rates, it must have a stop-loss mechanism to recover the excessive costs for extremely expensive patients.

2. Utilization management is critical in managed care contracting. Often hospitals will save money if they spend money to hire an intensivist (also called "Hospitalist") who can control the use of intensive care, monitored beds, and expensive medicines. Physicians and medical groups treating managed care patients need to encourage proper utilization.

3. Tips for Managed Care Contracts:

   a. Define the services to be provided. Defining what is included can be as important as setting the price. Address responsibility for paying for out-of-area services and emergency services.
   b. Set a fair price, if at all possible.
   c. Define who keeps deductibles and co-payments.
   d. Include stop loss limits on both capitated and fee-for-service discounted contracts.
   e. Assure your clients will get up-to-date information on who is covered and the plan will pay for mistakes if it turns out the patient is not covered.
   f. Assure payment will be made for pre-approved treatment, even if approval was given mistakenly.
   g. Address pharmacy benefits.
   h. Address and understand risk pools and withhold pools.
   i. Set the time for payments and interest penalties for late payment.
   j. Define who is responsible for utilization management and who will be liable in the event of a problem.
   k. Consider who you are dealing with - does your client need protections in case of insolvency? Is your client obligated to provide services regardless of whether your client is paid?
   l. Establish claim submission and appeal timelines.
   m. Control access to contract terms and the ability of the plan to assign benefits to others.
   n. Watch for the plan's ability to change policy and procedure manuals.
   o. Be aware of tiered network structures, a new strategy to direct utilization to less expensive facilities.
   p. Note the ability of plans to increase co-pays. Increased co-pays increase the risk of revenue collected.
   q. Address who will be responsible for the cost of new (and potentially expensive) treatment modalities including pharmaceutical products.
   r. Look for provisions that are omitted.

s. Scrutinize the definitions section. Compare the definitions to statutory definitions.

t. Talk to your operations and billing departments to identify previous payment problems that need to be addressed.

u. Review indemnity and confidentiality provisions for adequate protection and to make sure they apply to both parties.

v. Consider the choice of venue and dispute resolution processes. A lengthy dispute resolution process will delay payment. Provide for interest on payments not made in a timely manner.

w. Review any document, such as the provider manual, that is incorporated by reference.

x. Add a force majeure clause for unexpected disasters.

y. Review prompt pay statutes (Health & Safety Code § 1731.35, *et seq.*; Insurance Code § 10123.13).

F. Workers' Compensation.

1. Workers compensation payment does not come from the government, it comes from payors (insurers and self-insured employers) The Division of Workers' Compensation (DWC) monitors the administration of California workers' compensation claims, and provides administrative and judicial services to assist California employees. Employees are limited, under California workers compensation law, in the amount of compensation they can recover from their employer but the trade-off is the employer must pay for necessary and reasonable medical care and in some cases for lost wages without the employee proving the employer was negligent. California's WC system was at the center of intense debate and legislative activity during the period leading up to reforms in 2004 (SB 899). The Administrative Director of the DWC maintains an Official Medical Fee Schedule (OMFS) that establishes the maximum allowable fees for most medical services. The OMFS amounts apply unless the payor and provider have contracted for a different price. The OMFS for inpatient care provided by acute care hospitals is adapted from the Medicare payment system for these services.

G. Miscellaneous.

1. Cash accounts – although they are charged full rates (no discounts), often hospitals and physicians find that people who have no insurance also have no money.

2. Direct Provider Contracting – some major employers contract directly with providers to care for their employees. The employer may be self-insured (except for excess coverage for extremely high amounts). Care must be taken to avoid inadvertently creating a capitated arrangement that is subject to Knox-Keene regulations.

H. Hospital Liens

1. Automobile Insurance - another source of payment for accident victims, if liability is established. Hospitals and physicians will file liens against the recovery. Until recently, courts were consistent in enforcing those liens and giving them preference over other debts.

2. Hospitals have a statutory lien for unpaid hospital bills. Civil Code § 3045.1.

3. <u>Howell v. Hamilton Meats & Provisions</u> (Aug. 18, 2011). Patient was injured in an auto accident. PacifiCare paid the hospital bills at its contractual (reduced) rate. Patient sued the tortfeasor and sought to introduce evidence of the full charges. The trial court allowed the evidence pursuant to the collateral source rule (collateral payments from independent source does not reduce damages payable by the tortfeasor.) The case was appealed and the Supreme Court held that the plaintiff could not recover any more than the amount paid by Pacificare.

4. There was a similar result in the Medi-Cal context. (<u>Hanif v. Housing Authority</u> (1988) 200 Cal. App. 3d 635 (1988)).

VIII. FRAUD AND ABUSE STATUTES

A. The Anti-Kickback Statute (40 U.S.C. § 1320a-7b(b)) and Safe Harbors

1. Criminal. The Anti-Kickback Statute makes it a felony to offer, pay, solicit or receive any remuneration in return for business for which payment may be made under a federal health care program. There are criminal and civil penalties for violation as well as exclusion from the Medicare and/or Medicaid program. Penalties are up to $25,000 or up to 3 years in prison or both. A violation can also be prosecuted under the Civil Monetary Penalties law, which has fines of up to $50,000 per act and up to 3 times the amount of payments received from the government. Both the party who solicits, offers or pays remuneration and the party that receives the remuneration are guilty of the violation.

2. The Anti-Kickback Statute offers "Safe Harbors" for some activity that strictly meet the requirements of the safe harbor.

3. Often-used safe harbors are those for:

    a. Space and Equipment
    b. Employment
    c. Personal Services
    d. Physician Recruitment

4. Examples: changing ownership percentage based upon referrals, contracts for little or no services, below fair market value lease, and post-closing earn-outs based upon referrals.

5. Violation if one purpose is to influence referrals. Does not have to fall in safe harbor, but subject to scrutiny.

B. The Stark Law (42 U.S.C. § 1320a-7b(b)) and Exceptions

1. Civil. A physician may not refer Medicare or Medicaid patients for designated health services to an entity with which the physician (or an immediate family member) has a financial relationship unless an exception applies. An entity may not present, or cause to be presented, a claim for payment for services provided as a result of a prohibited referral. If a financial arrangement between a physician and an entity does not qualify for an exception, all of the physician's referrals to the entity are tainted. Penalties include: denial of payment, refund of monies received, exclusion from Medicare and/or Medicaid, civil monetary penalties up to $100,000 and False Claims Act liability.

2. Applies to designated health services as defined by Current Procedural Terminology (CPT) Codes:

a. Clinical laboratory services
b. Physical therapy services
c. Occupational therapy and speech pathology services
d. Radiology and certain other imaging services
e. Radiation therapy services and supplies (including nuclear medicine)
f. Durable medical equipment and supplies
g. Parenteral and enteral nutrients, equipment, and supplies
h. Prosthetics, orthotics and prosthetic devices and supplies
i. Home health services.
j. Outpatient prescription drugs; and
k. Inpatient and outpatient hospital services.

3. Financial arrangements may be direct or indirect, depending upon whether at least one person or entity is interposed between the DHS entity and the referring physician.

4. Example: when a medical device manufacturer replaces a malfunctioning device, it issues a credit. Hospitals are required to pass on the credits to Medicare, which covers the bill for surgeries to implant the replacement device. The OIG's position is that the hospital owes the credit even if it does not collect it from the manufacturer.

C. False Claims Act (31 U.S.C. § 3729-3733).

1. It is illegal to submit claims for payment to Medicare or Medicaid that are false or fraudulent. Fines may be up to 3 times the programs' loss plus $11,000 per claim filed. Each instance of an item or service billed to Medicare or Medicaid counts as a claim. No specific intent is required. Examples are filing for services at a higher rate (upcoding) or failing to return overpayments.

D. Criminal False Claims Act (18 U.S.C. § 287).

1. Criminal penalties for submitting false claims include imprisonment and criminal fines.

E. Exclusion Statute (42 U.S.C. § 1320a-7).

1. Excluded physicians may not bill directly or indirectly for services to Medicare or Medicaid patients. See http://exclusions.oig.hhs.gov

F. Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a).

1. Presenting a false or fraudulent claim or where payment may not be made, violating the Anti-Kickback Statute, violating Medicare assignment provisions, violating Medicare provider agreement, failing to conduct a medical screening exam in the ER, or making false statements in connection with federal health care programs.

G. Spier Law.

1. California's self-referral statute, known as the Spier law, Business & Professions Code § 650, prohibits self-referrals. It is similar to, but not identical to the Stark law.

H. Other Tools.

1. California's insurance code is the basis for an action by the state against hospitals for overcharging insurance companies for anesthesia services. <u>State of California ex rel. & Rockville Recovery Associates Ltd. v. MultiPlan Inc.</u>

IX. ANTITRUST LAW

A. The Sherman Act

1. The Sherman Act prohibits the unlawful restraint of trade. The law itself suggests every contract or combination that restricts trade is illegal; however the judicial gloss over the years has narrowed the reach to those

contracts or combinations that "unreasonably" restrain trade. There are two main categories of activities:

a. Per Se Violations: Some activities are deemed so pernicious that they are automatically deemed to violate the antitrust laws - regardless of the motives and other merits. For example, price fixing among competitors is per se illegal, even when the motive was to set maximum prices to save consumers from price gouging. (See Maricopa.)

b. Rule of Reason: All other activities may be justified, on balance. Accordingly, the courts will evaluate the rationale for the activity, applying the "rule of reason" to determine whether an activity is justified by legitimate reasons, even if one effect is to restrain trade.

2. In general, antitrust violations require "concerted action" between two players — e.g., a conspiracy between two competitors to exclude a third player. However, a single entity may violate the antitrust laws by actions such as creating a monopoly using illegal means (not simply a superior product), tying the sale of a product in which the organization has monopoly power with a weaker product, or by illegally dumping products on the market at below market prices.

3. Also, antitrust violations require that the violator have "market power" — a key concept meaning that the players singly or together have sufficient clout in the market to affect prices through their actions.

B. Mergers and Acquisitions.

1. Hospital mergers are subject to challenge under Section 7 of the Clayton Act or Section 1 of the Sherman Act. Challenges are analyzed using the rule of reason approach. Section 7 of the Clayton Act prohibits mergers or consolidation where the effect "may be substantially to lessen competition, or to tend to create a monopoly." The enforcement agencies seek to determine whether the proposed transaction will enable the merged parties to raise prices or restrict prices or otherwise reduce competition.

2. Because many hospital mergers involve significant assets, the Hart-Scott-Rodino Antitrust Improvement Act of 1976 often requires proposed hospital merger parties to provide enforcement agencies with pre-merger notification and observe a statutorily mandated thirty-day waiting period prior to completing their proposed combination. During the waiting period, the agencies examine the competitive effects of the consolidation and may impose actions to address any antitrust concerns they may have.

C. Managed Care.

1. The Justice Department filed an anti-trust lawsuit against Blue Cross Blue Shield of Michigan in October, 2010, challenging its policy of requiring "most favored nation" clauses in its provider contracts. The case is before the Sixth Circuit.

X. DATA PRIVACY AND SECURITY

A. Health Insurance Portability and Accountability Act ("HIPAA").

1. HIPAA's original purpose was to address the portability of health care insurance for employees transferring jobs. Today it is best known for revolutionizing how health care providers address the privacy and security of health care information.

2. HIPAA's privacy standards impose regulations designed to protect the privacy and confidentiality of individually identifiable health information (also referred to as "Protected Health Information" or "PHI") by directly regulating the use and disclosure of such information by health care providers that transmit health as well as health plans and health care clearing houses (collectively, "covered entities").

3. The privacy standards also impact the business arrangements between health care entities covered by HIPAA and their business associates that receive PHI from the covered health care entities.

4. In general, HIPAA's privacy regulations require health care providers to:

a. Only disclose PHI to the "minimum amount necessary". This impacts who in a health care institution can have access to PHI and also limits how PHI can be used in various hospital activities including fund raising and marketing.
b. Except for certain specifically allowed uses, only disclose PHI pursuant to the patient's authorization.
c. Provide their patients with a Notice of Privacy Practices that describes how PHI is used and disclosed by the health care provider and informs patients of their rights with respect to their PHI.
d. Appoint privacy officers to deal with HIPAA related issues.
e. Improve the security and privacy controls of health care information by implementing safeguards to protect PHI from unintentional or intentional use or disclosure.

f. Enter into Business Associate Agreements with entities that are given access to PHI in order to provide a service on behalf of the covered entity. This includes law firms providing services to health care providers.
g. Keep track of disclosures of PHI.
h. Allow patients to "opt out" of receiving certain communications or to request certain restrictions regarding use or disclosure of PHI.
i. Train employees on HIPAA's requirements and establish sanctions for those employees who don't comply with the law.

5. HIPAA also imposes new limitations as to what can be disclosed to media and others that call for information about hospital patients. For a good overview of what information can be provided by hospitals in response to media inquiries, see the California Hospital Association brochure titled Guide to Release of Patient Information available at www.calhospital.org.

6. Penalties for Violations.

a. Civil monetary penalties for failure to comply with requirements and standards include fines up to $100 per violation with a calendar year cap of $25,000 for multiple violations of single provision.
b. Criminal Penalties include fines of up to $50,000 and/or imprisonment for up to one year for any person who "knowingly and in violation" of the law uses or causes to be used a unique health identifier, obtains individually identifiable health information or discloses individually identifiable health information.
c. If information is obtained under false pretenses, fines are up to $100,000 and/or imprisonment for up to five years.
d. If committed with intent to sell, transfer, or use information for commercial advantage, personal gain, or malicious harm, fine of up to $250,000 and/or imprisonment for up to 10 years.

7. HIPAA establishes a floor for privacy standards — not a ceiling. State laws and regulations may be more restrictive. Providers must conform to whichever law is more stringent.

8. HIPAA extends beyond privacy regulations. HIPAA also imposes Security and Electronic Signature Standards. Regulations in this area cover physical safeguards to guard data integrity, confidentiality, the protection of computer systems from fire and other environmental disasters, as well as, from intruders.

B. Health Information Technology for Economic Clinical Health Act (HITECH)

1. The HITECH Act is intended to strengthen privacy and security protection of health information. Proposed rules were issued on July 8, 2010. These proposed rules modify the obligations of a business associate. It would require a business associate to use or disclose PHI only as permitted by the Privacy Rule or Enforcement Rule and only consistent with its obligations under its business associate agreement with the covered entity. The proposed rule would require a business associate to: comply with the HIPAA Security Rule with respect to electronic PHI, report breaches of unsecured PHI to covered entities as required by the HHS Breach Notification rule, and ensure that any subcontractors agree to the same restrictions.

C. California Privacy Statutes

1. Civil Code section 1798.82 applies to "any person or business that conducts business in California, and that owns or licenses computerized data that includes personal information." Personal information is any unencrypted information that contains an individual's first name or first initial and last name in combination with either any of the following: (1) social security number, (2) driver's license number of California identification care number, (3) account number, credit or debit card number, in combination with any required security code, access code, or password that would permit access to an individual's financial account, (4) medical information, or (5) health insurance information.

2. Disclosure of a security breach is required "in the most expedient time possible and without unreasonable delay" to any resident of California whose unencrypted personal information "was, or is reasonably believed to have been, acquired by an unauthorized person."

3. If a notice of breach is required, it must contain the following information:

   a. The name and contact information of the reporting person or business;
   b. A list of the types of personal information that were or are reasonably believed to have been the subject of a breach.
   c. If the information is possible to determine at the time the notice is provided, then any of the following: (i) the date of the breach, (ii) the estimated date of the breach, or (iii) the date range within which the breach occurred. The notification shall also include the date of the notice.

d. Whether notification was delayed as a result of a law enforcement investigation, if that information is possible to determine at the time the notice is provided.

e. A general description of the breach incident, if that information is possible to determine at the time the notice is provided.

f. The toll-free telephone numbers and addresses of the major credit reporting agencies if the breach exposed a social security number or a driver's license or California identification card number.

4. At the discretion of the person or business, the security breach notification may also include any of the following:

a. Information about what the person or business has done to protect individuals whose information has been breached.

b. Advice on steps that the person whose information has been breached may take to protect himself or herself.

5. If over 500 patients are affected, a copy of the notice must go to the Attorney General.

6. Health & Safety Code § 1280.5 applies to breaches that occur at licensed health facilities.

7. California Medical Information Act, Civil Code § 56.36 applies to businesses that access or use medical information.

D. Social Media

1. Potential liability for HIPAA violations when employees discuss patients and/or their medical conditions online.

XI. EMTALA

A. Emergency Medical Treatment and Labor Act.

1. Applies to hospitals with an emergency department that participate in the Medicare program. Hospitals are responsible for providing appropriate screening to anyone presented for treatment to determine if an emergency medical condition exists, and to stabilize any such emergency condition before discharging or transferring the patient.

2. A participating hospital may not delay provision of an appropriate medical screening examination required under subsection (a) of this section or further medical examination and treatment required under subsection (b) of this section in order to inquire about the individual's method of payment or insurance status.

3. The hospital must provide care until the condition ceases to be an emergency or until the individual is properly transferred to another facility.

4. A hospital violates EMTALA by transferring an unstable patient without implementing an appropriate transfer.

5. A discharge before the patient is treated or stabilized is a violation.

6. A hospital's obligation ends when:

   a. No emergency medical condition exists
   b. An emergency medical condition exists and the individual is appropriately transferred to another facility, or
   c. An emergency medical condition exists and the individual is admitted to the hospital for further stabilizing treatment.

7. Emergency services and care shall be rendered without first questioning the patient or any other person as to his or her ability to pay therefore. However, the patient or his or her legally responsible relative or guardian shall execute an agreement to pay therefore or otherwise supply insurance or credit information promptly after services are rendered.

8. The tort of patient abandonment is the unilateral severance of the professional relationship between the provider and the patient without reasonable notice at a time when there is still the necessity of continuing attention.

B. On-call Issues

1. EMTALA Requires that hospitals maintain a list of physicians who are available on-call to provide necessary services to patients coming to the emergency room

XII. PPACA AND ACCOUNTABLE CARE ORGANIZATIONS

A. Medicare Shared Savings Program

1. Section 3022 of PPACA creates a Medicare shared savings program to begin no later than January 1, 2012. It is a voluntary program. Entities called Accountable Care Organizations (ACOs) will be formed to coordinate treatment of patients.

2. The ACO must sign an agreement with CMS to participate in the Shared Savings Program for three years and must accept responsibility for at least 5,000 Medicare beneficiaries. Beneficiaries will be assigned to the ACO by CMS and the ACO will not know which beneficiaries are assigned to it.

Beneficiaries are assigned to a primary care physician. A primary care physician may only be in one ACO.

3. Beneficiaries may choose not to be in the ACO. Providers will receive fee-for-service payments under Parts A and B, and will be eligible to receive additional payments if the ACO meets certain quality and savings benchmarks. Conversely, if those benchmarks are not met, the ACO could be liable for the losses.

4. CMS is proposing two different risk models. Under the first track, an ACO could operate on a shared savings basis (upside) only for the first two years and be eligible for up to 50% of savings, but would assume risk for any shared losses (downside) in the third year (up to 7.5% of expenditure benchmark). Under the second track, an ACO would share in both savings and losses starting in the first year and at higher rates (maximum of 60% of savings and 10% of expenditure benchmarks).

XIII. PPACA CHANGES TO MEDICARE FRAUD ENFORCEMENT

A. Qui Tam Actions.

1. Publicly Available. Until now, "qui tam" or "whistleblower" actions were immediately dismissed if they were based on information that is "publicly available"

2. Original Source. Previously whistleblowers could bring actions based on public disclosure only if they "had direct and independent knowledge" of the information and provided to the government before filing suit. Under PPACA, the whistleblower is only required to have knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions.

3. No retaliation against whistleblowers.

B. Health Care Fraud Prevention and Enforcement Action Team (HEAT).

1. Analyzes Claim Data to Determine Overpayments

C. False Claims Act.

1. The False Claims Act generally provides that a person can be subject to a fine and/or imprisonment for up to five years when he or she, in any matter involving a health care program, "knowingly and willfully (1) falsifies, conceals, or covers up by a trick, scheme, or device a material fact; or (2) makes any materially false, fictitious, or fraudulent statements or

representations, or makes or uses a materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry."

D. Self-Reporting.

1. CMS developed a self-referral disclosure protocol whereby providers and suppliers can report actual or potential violations of the Stark Law.

E. Expansion of Recovery Audit Contractor (RAC) Programs.

XIV. PPACA MEASURES FOR QUALITY IMPROVEMENT

A. Quality Improvement Initiatives.

1. Value-Based Purchasing. Medicare will tie the amount of Medicare payment to each acute care hospital to the hospital's performance on certain quality standards.

2. Hospital Acquired Conditions. Beginning on October 1, 2014, hospitals that are in the top quartile of all hospitals, relative to the national average, of HACs for certain high-cost and common conditions will be subject to a reduction in the Medicare payment for inpatient services. Information regarding HACs of each hospital will be made available to the public on the Hospital Compare Web site.

3. Hospital Readmission. Beginning on October 1, 2012, hospitals that have a high rate of potentially preventable Medicare readmissions will be subject to Medicare payment reductions.

4. Electronic Records. The HITECH Act provided for substantial Medicare and Medicaid incentives for hospitals and physicians to adopt electronic health records (EHRs). In order to receive incentives payments, providers must satisfy standards of "meaningful use" of certified EHR systems.

5. Reporting Overpayments. Providers must report and return identified overpayments to, as appropriate, HHS, the State, an intermediary, a carrier, or a government contractor by the later of:

   a. 60 days from the date the overpayment is identified; or
   b. The date any corresponding cost

XV. OTHER LAWS IMPACTING HEALTH CARE

A. Intellectual Property.

1. Consider whether the name, procedures, brochures and other materials of inventions created by employees can be protected under the intellectual property laws. Do your clients have any right to protect their investments? Consider what agreements employees are asked to sign concerning intellectual property rights.

B. Human Resources/Labor.

1. Increasingly, wage and hour laws relating to exempt v. non-exempt status of employees or payment for overtime are confronting employers. Settling these cases can be extremely expensive.

2. California's nurse staffing ratio regulations require defined staffing levels at "all times" in hospitals. Compliance with these laws is mandatory. (AB 394).

C. Hazardous Wastes.

1. Health care providers must comply with strict hazardous waste laws.

D. Non-Discrimination

1. Hospitals are subject to Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975 and American with Disabilities Act of national origin or age or handicap.

2. Genetic Information Non-Discrimination Act (GINA) recently adopted in California.

SPECIAL THANKS

Suzanne Fullerton Van Hall's outline for the California Society of Healthcare Attorneys' 2001 "Back to Basics" was the original material for this course. Carlisle ("Ky") C. Lewis, III, added his insight and created the 2005 edition. This outline consists of Suzanne's and Ky's material with updates to reflect changes in the law. Grateful appreciation goes to Ky and Suzanne for sharing their knowledge and expertise with the CSHA membership.

Quick Reference to Health Care Terms

ACO Accountable Care Organization - a group of health care providers (e.g. primary care physicians, specialists and hospitals) that have entered into a formal arrangement to assume collective responsibility for the cost and quality of care of a specific group of patients and that receive financial incentives to improve the quality and efficiency of health care.

Anti-Kickback A Federal law that prohibits the paying or receiving of remuneration in exchange for the referral of patients or businesses paid by a Federal health care program.

APC Ambulatory Payment Classifications are the United States government's method of paying for facility outpatient services for the Medicare (United States) program. APCs are an outpatient prospective payment system applicable only to hospitals.

Capitation The payment of a per capita amount for a defined package of health care services. A specific dollar amount per member per month is paid to providers or organizations of providers for which they provide specific services, regardless of the quantity of services necessary to meet the health needs of the defined population.

CMS Centers for Medicare & Medicaid Services (CMS) (formerly: Health Care Financing Administration: HCFA)—The Centers for Medicare & Medicaid Services (CMS) administers the Medicare and Medicaid programs.

CPT Current Procedural Terminology (CPT) - A standardized mechanism of reporting services using numeric codes as established and updated annually by the AMA. It is the basis of the Medicare coding system for physician's services. A medical code set of physician and other services, maintained and copyrighted by the American Medical Association (AMA), and adopted by the Secretary of HHS as the standard for reporting physician and other services on standard transactions.

DRG Diagnostic Related Group - A hospital classification system that groups patients by common characteristics requiring treatment. Its intent was to identify the "products" that a hospital provides. DRGs are assigned by a "grouper" program based on ICD (International Classification of Diseases) diagnoses, procedures, age, sex, discharge status, and the presence of complications or comorbidities. DRGs have been used in the US since 1982 to determine how much Medicare pays the hospital for each "product", since patients within each category are similar clinically and are expected to use the same level of hospital resources.

DMHC – California Department of Managed Health Care - regulates capitation-based health plans in the state of California.

DHCS Department of Health Care Services. The DHCS finances and administers a number of individual health care service delivery programs, including the California Medical

Assistance Program (Medi-Cal).

EMTALA Emergency Medical Treatment and Labor Act (EMTALA) - An act pertaining to emergency medical situations. EMTALA requires hospitals to provide emergency treatment to individuals, regardless of insurance status and ability to pay.

ERISA Employee Retirement Income Security Act of 1974 (ERISA) - Also called the Pension Reform Act, this act regulates the majority of private pension and welfare group benefit plans in the U.S. It sets forth requirements governing, among many areas, participation, crediting of service, vesting, communication and disclosure, funding, and fiduciary conduct. ERISA exempts most large self-funded plans from state regulation.

HIPAA Health Insurance Portability and Accountability Act of 1996 (HIPAA) - A Federal law that allows persons to qualify immediately for comparable health insurance coverage when they change their employment relationships (COBRA). DHHS has issued HIPAA privacy regulations (the HIPAA Privacy Rule) as well as other regulations under to protect the security and privacy of personally identifiable health care information (the HIPAA Security Rule).

HITECH Subtitle D of the Health Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment Act of 2009, addresses the privacy and security concerns associated with the electronic transmission of health information. This subtitle extends the complete Privacy and Security Provisions of HIPAA to business associates of covered entities. This includes the extension of newly updated civil and criminal penalties to business associates. These changes are also required to be included in any business associate agreements with covered entities. Another significant change is the new breach notification requirements. This imposes new notification requirements on covered entities, business associates, vendors of personal health records (PHR) and related entities if a breach of unsecured protected health information (PHI) occurs.

Joint Commission (JCAHO) formerly: Joint Commission on Accreditation of Healthcare Organizations—The Joint Commission (JCAHO) is a private, nonprofit organization that evaluates and accredits hospitals and other health care organizations providing home care, behavioral health care, ambulatory care and long-term care services.

Knox-Keene The Knox-Keene Health Care Service Plan Act of 1975, as amended, is the set of laws passed by the California Legislature to regulate HMOs within the State.

MICRA Medical Injury Compensation Reform Act of 1975 limits damages recoverable in medical malpractice suits in California.

OIG Office of Inspector General (OIG) - The office responsible for auditing, evaluating and criminal and civil investigating for HHS, as well as imposing sanctions, when necessary, against health care providers. See also Fraud, FBI, and Dept. of Justice.

PPS Prospective Payment System (PPS) A method of financing health care that mandates

payments in advance for the provision of services and is based on diagnostic related groups.

QIO Quality Improvement Organization (QIO) Organization under contract to review quality and cost issues for Medicare. Required to oversee Medicare HMOs. Formerly known as a peer review organization. Can also be used in a more general sense to refer to any independent quality review organization.

RAC Recovery Audit Contractor, or RAC, program was created through the Medicare Modernization Act of 2003 (MMA) to identify and recover improper Medicare payments paid to healthcare providers under fee-for-service (FFS) Medicare plans. In section 306 of the Medicare Modernization Act of 2003, the United States Department of Health and Human Services (DHHS) was directed to conduct a three-year demonstration program to detect and correct improper payments in the Medicare FFS program. DHHS, through its Centers for Medicare and Medicaid Services (CMS) branch, began the program in 2005, using Recovery Audit Contractors to perform the actual work of reviewing, auditing, and identifying improper Medicare payments.

RBRVS - Resource-Based Relative Value Scale - Medicare fee schedule for physician services that set a uniform payment in each geographic area for most of the approximately 7,000 medical procedures.

Stark The commonly used name for Federal laws and regulations that ban physician referral to entities with which the physician has a financial relationship.

Sources:

http://www.rwjf.org/qualityequality/glossary.jsp; Robert Wood Johnson Foundation Glossary of Health Care Quality Terms

Pam Pohly's Net Guide: Glossary of Terms in Managed Care
www.pohly.com/terms_c.html

Delaware Healthcare Association
www.deha.org/Glossary/GlossaryA.htm#top

Wikipedia
www.wikipedia.org

Medicare Glossary
http://www.medicare.gov/Glossary/a.html