OPPORTUNITIES IN HEALTH LAW

Career Paths for New and Experienced Counsel

State Bar of California
Business Law Section

DATE: January 15, 2015
TIME: 12:00 PM to 1:00 PM

PRESENTER:
Craig B. Garner, Esq.

This Program Offers One Hour of MCLE Participatory Credit
INTRODUCTION

- The 2010 Affordable Care Act has transformed our nation’s health care system, creating myriad opportunities for attorneys and professionals along the way.

- Now more than ever, attorneys in most fields of practice are destined to overlap with health care law.

- Interested in making the switch from another specialty, or expanding your health law practice?
SECTIONS OF THE STATE BAR OF CALIFORNIA

- Antitrust and Unfair Competition
- Business Law
- Criminal Law
- Environmental Law
- Family Law
- Intellectual Property Law
- International Law
- Solo and Small Firm
- Taxation
- Trusts and Estates
- Workers’ Compensation
BUSINESS LAW SECTION STANDING COMMITTEES

- Agribusiness
- Business Litigation
- Commercial Transactions
- Consumer Finance Services
- Corporations
- Cyberspace Law
- Financial Institutions
- Franchise Law
- Health Law
- Insolvency Law
- Insurance Law
- Nonprofit Organizations
- Opinions
- Partnerships and Limited Liability Companies
ETHICAL CONSIDERATIONS

California Rules of Professional Conduct, Rule 3-110:

Absent the requisite skill to accommodate a client’s needs, an attorney may still engage and adhere to the statutory definition of competence by “associating with or, where appropriate, professionally consulting another lawyer reasonably believed to be competent” or “by acquiring sufficient learning and skill before performance is required.”
ANTITRUST
THE STATUTORY FRAMEWORK


- Clayton Act, § 7 (15 U.S.C. § 18) prohibits mergers and acquisitions where the effect may be “substantially to lessen competition” or “to tend to create a monopoly.”

LOWER COSTS, BETTER QUALITY

“Over the years, health care service has been treated pretty much as a "natural monopoly." It has been assumed that a community could support only so many hospitals; that providers just naturally control supply and demand. . . . Isn't it just possible, some are asking, that turning competition loose, at least in some sections, may not only lower the costs of health care but improve its quality?”

LOWER COSTS, BETTER QUALITY (CONTINUED)

“The success of health care reform in the United States depends on the proper functioning of our market-based health care system. Antitrust laws play a crucial role in ensuring that consumers benefit.”

FEDERAL AGENCY INTERVENTION


- FTC blocked a hospital merger in Ohio; Sixth Circuit upheld the decision. *Promedica Health System, Inc. v. Federal Trade Comm’n*, 749 F3d 559 (6th Cir. 2014).
JUDICIAL DECISIONS


PHYSICIAN STAFF PRIVILEGES

- The “junk food of antitrust health care litigation” refers to the hundreds of physicians who have been denied staff privileges at hospitals or had their privileges revoked, suspended or limited. Most cases have been unsuccessful.

- *But see Boczar v. Manatee Hospitals & Health Systems*, 993 F.2d 1514 (11th Cir. 1993) (upholding a jury finding an anticompetitive intend and effect based on the hospital’s pretextual explanations defending its actions).

- Blame rival physicians on the hospital’s medical staff. See, e.g., *Oltz v. St. Peter’s Community Hosp.*, 861 F.2d 1440 (9th Cir. 1988).
ON THE HORIZON

- Federal and state agency intervention in hospital mergers and acquisitions will escalate.

- Physician and hospital consolidations will face legal challenges and increased scrutiny in vertical markets.

- Keep track of the increasing number of federally approved accountable care organizations ("ACOs") and commercial ACOs.
BUSINESS LITIGATION
THE EXPANSIVE MEDICARE REGULATIONS

The last 50 years have seen Medicare emerge to find itself the blueprint upon which the nation’s health care system is based. As a body of law, Medicare consists of the following:

- Title 42 of the United States Code
- Title 42 of the Code of Federal Regulations
- The CMS Online Manual System (http://www.cms.hhs.gov)
- The Medicare Administrative Appeals Process
- Federal Court decisions
THE FIVE LEVELS OF MEDICARE APPEALS

Section 1869 of the Social Security Act and 42 C.F.R. Part 405, Subpart I, contain the procedures for conducting appeals of claims in Original Medicare (Parts A and B).

- Redetermination by a CMS contractor (carrier, fiscal intermediary or Medicare Administrative Contractor).
- Reconsideration by a Qualified Independent Contractor.
- Hearings before an Administrative Law Judge within the Office of Medicare Hearings and Appeals in HHS.
- Review by the Appeals Council within the Department Appeals Board of HHS.
- Judicial review in federal district court.
EXHAUSTION OF ADMINISTRATIVE REMEDIES

The Medicare Act sets forth very stringent channeling requirements to ensure a proper exhaustion of administrative remedies, which comes at a price. Nevertheless:

“In the context of a massive, complex health and safety program such as Medicare, embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations, any of which may become the subject of a legal challenge in any of several different courts, paying this price may seem justified.” Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 13 (2000).
YOU CANNOT REFUSE THE RIGHT TO SERVE

- In an effort to counteract “patient dumping,” wherein hospitals refuse to treat people due to lack of insurance or inability to pay, Congress passed the Emergency Medical Treatment and Active Labor Act (EMTALA).

- EMTALA requires every hospital receiving federal funding to treat any patient with an emergency condition in such a way that, upon the patient’s release, no further deterioration of the condition is likely.
TREAT UNTIL STABLE.

- No hospital may release a patient with an emergency medical condition without first determining that the patient has been stabilized, even if the hospital properly admitted the patient.

- Under EMTALA, patients requesting emergency treatment can only be discharged under their own informed consent or when their condition requires the services of another hospital better equipped to treat the patient’s concerns.
. . . EVEN IF YOU CANNOT COLLECT

Many industries outside of health care take a different approach when a consumer of goods (e.g., a patient) fails to perform (i.e., pay) under an oral or written agreement:

- Larceny (Cal. Penal Code § 487)
- Diversion of Funds (Cal. Penal Code § 484b)
- Protection from Buyer Insolvency (Cal. Commercial Code § 2702)

- No crime eviscerates the power of EMTALA
ON THE HORIZON

- Hospitals and Health Systems v./adv. Health Plans
- Patients v./adv. Hospitals and Health Systems
- Patients v./adv. Health Plans
- Hospitals and Health Systems v./adv. Physicians and Group Practices
CRIMINAL LAW
OFFICE OF THE INSPECTOR GENERAL ("OIG"), FISCAL 2014 REPORT TO CONGRESS

- Recovered $4.9 billion in improperly spent federal health care funds ($4.1 billion in investigative work, including $1.1 billion in Medicaid restitution).

- Excluded 4017 individuals and entities from participation in federal health care programs.

- Reported 971 criminal actions against individuals or entities (Medicare Fraud Strike Force resulting in 228 filing of charges).
FROM THE OIG WEBSITE

- December 8, 2014 (Los Angeles): A physician was sentenced to 24 months in federal prison (related to medically unnecessary power wheelchairs and other DME).

- November 19, 2014 (Valencia): A doctor who ran pain management clinic agreed to pay $1.2 million to resolve allegations of fraudulent billings.

- October 8, 2014 (Los Angeles): An indictment was unsealed charging two managers and operators of three medical clinics with Medicare fraud.
FROM THE OIG WEBSITE (CONTINUED)

- September 22, 2014 (Long Beach): The former owner of a medical supply company was sentenced to serve 30 months in prison and ordered to pay restitution for his role in scheme to provide unnecessary power wheelchairs.

- September 16, 2014 (Los Angeles): The general manager of an ambulance company pleaded guilty to conspiracy to commit Medicare fraud.

- September 2, 2014 (San Francisco): The United States filed a civil False Claims Act complaint against the owners, operators and manager of two nursing homes.
CALIFORNIA OFFICE OF THE ATTORNEY GENERAL, BUREAU OF MEDI-CAL FRAUD & ELDER ABUSE

- State bureau oversees medical doctors, dentists, mid-level practitioners, medical supply companies and nursing homes.

- Protects patients in nursing homes and other long-term care facilities from abuse or neglect.

- Mandate reporters under state law for (1) child abuse/neglect (Cal. Penal Code § 11165.7), (2) elder/dependent adult abuse (Cal. Welfare & Inst. Code §§ 15630, 15610.37) and (3) injury by firearm or assault/abuse (Cal. Penal Code § 11160).
OTHER FRAUD CLAIMS

- Health Care Fraud, 18 U.S.C. § 1347
- Mail and Wire Fraud, 18 U.S.C. §§ 1341, 1343
- False Statements Relating to Health Care Matters, 18 U.S.C. § 1035
- False Statements Generally, 18 U.S.C. § 1001
- Obstruction of Justice, 18 U.S.C. § 1518
ENVIRONMENTAL LAW
AEROSOL TRANSMISSIBLE DISEASES

- Health care facilities are at increased risk for transmission of aerosol transmissible disease ("ATD"), a disease or pathogen for which droplet or airborne precautions are required.

- Reportable aerosol transmissible diseases include diseases/pathogens requiring airborne infection isolation (e.g., smallpox, tuberculosis, measles) and diseases/pathogens requiring droplet precautions (e.g., meningitis, mumps, pneumonia, pertussis).

8 C.C.R. § 5199
CAL/OSHA

- The Division of Occupational Safety and Health ("DOSH") protects workers from health and safety hazards on the job in most workplaces throughout California.

- The Hospital Patient and Health Care Worker Injury Protection Act requires certain hospitals to adopt safe patient handling policies.

- Cal/OSHA’s “Elevator Unit” maintains “a vigilant system to meet [its] obligations to inspect and enforce code compliance of elevators and other conveyances.”
UNDERGROUND STORAGE TANK PROGRAM

- An underground storage tank ("UST") is defined by law as "any one or combination of tanks, including pipes connected thereto, that is used for the storage of hazardous substances and that is substantially or totally beneath the surface of the ground."

- The purpose of the UST program is to protect public health and safety and the environment from the release of petroleum and other hazardous substances from tanks.

- Hospital underground storage tanks must be monitored and tested to ensure compliance with seismic safety regulations.
SEISMIC SAFETY

- California Office of Statewide Health Planning and Development ("OSHPD") oversees seismic compliance for California hospitals.

- OSHPD enforces the Alfred E. Alquist Seismic Safety Act which establishes a seismic safety building standards program under its jurisdiction for hospitals built on or after March 7, 1973.
SEISMIC SAFETY (CONTINUED)

- The Act emphasizes that essential facilities, such as hospitals, should remain operational after an earthquake.

- Hospitals built in accordance with the standards of the Act resisted the January 1994 Northridge earthquake with minimal structural damage, while several facilities built prior to the act experienced major structural damage and had to be evacuated.
OTHER AREAS OF FOCUS

- **Patient Sharps Waste Disposal**: Applies to health care businesses that generate “Sharps” (items used to puncture skin, such as hypodermic needles and syringes).


- **Radiologic Health Branch**: Oversees radiation workers’ safety, licensing of radioactive materials, registration of X-ray machines, and other related activities.
FAMILY LAW
INDIVIDUAL AND FAMILY INSURANCE COVERAGE

- Essential Health Benefits
- Fair Health Insurance Premiums
- End of Preexisting Conditions
- Coverage for Adult Child Until the Age of 26
- Guaranteed Availability
- Health Insurance Exchanges
- Medicaid Expansion
OTHER PROGRAMS

- **The Health Care Program for Children in Foster Care (HCPCFC)** is a public health nursing program located in county child welfare service agencies and probation departments to provide public health nursing expertise in meeting the medical, dental, mental and developmental needs of children and youth in foster care.

- California’s **Access for Infants and Mothers (AIM)** program helps those without insurance who are not receiving no-cost Medi-Cal or Medicare Part A and Part B to cover pregnancy.
CHILDREN AND ADOLESCENT HEALTH PROGRAMS

- American Indian Infant Health Initiative (AIIHI)
- California’s Asthma Public Health Initiative
- California’s Children’s Services
- Child Health and Disability Prevention
- Fatal Child Abuse
- Healthy Families/Healthy Kids
- Indian Health Program
- Newborn Screening Program
INTELLECTUAL PROPERTY LAW
HIPAA AND HITECH

- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") governs the management of protected health information ("PHI") by covered entities (such as hospitals) and their business associates.

- The Health Information Technology for Economic and Clinical Health Act ("HITECH"), contained within the American Recovery and Reinvestment Act of 2009, altered the scope of HIPAA and its application to business associates, as well as the resulting penalties thereunder.
DATA BREACH

- Existing privacy laws require nearly every health care related electronic device to employ encryption algorithms, from a home facsimile or copy machine to all institutional servers.

- Laptops and other portable devices must default to unreadable ciphertext, a protocol far beyond the ordinary login password.
DATA BREACH (CONTINUED)

Affecting almost 700,000 health care entities, the fines for data breaches can now exceed $1.5 million, as well as the estimated costs involved in order to comply:

- Breach Notifications: $14.5 million
- Toll-Free Notification Lines: $3.9 million
- Business Associates: $150 million
- Notification to Patients of Privacy Practices: $56 million
SUTTER HEALTH

- Class action lawsuits filed after a computer with personal data on 4.24 million patients was stolen from a local office in October 2011. Claims for damages exceeded $4 billion.

- In July 2014, a California Court of Appeal dismissed the class action on the basis there was no proof anybody actually looked at the stolen information following the theft.

- In October 2014, the California Supreme Court denied review.

*Sutter Health v. Superior Court, 227 Cal. App. 4th 1546 (2014).*
LABOR AND EMPLOYMENT
AREAS OF OVERLAP

- Mergers and acquisitions
- Employer Mandate
- Collective bargaining and trade unions
- Wrongful termination lawsuits
- Whistleblower Protection
WHISTLEBLOWER PROTECTION

California encourages employees to notify an appropriate government or law enforcement agency, person with authority over the employee, or another employee with authority to investigate, discover, or correct the violation or noncompliance, and to provide information to and testify before a public body conducting an investigation, hearing or inquiry, when they have reason to believe their employer is violating a state or federal statute, or violating or not complying with a local, state or federal rule or regulation.
WHO IS PROTECTED?

- Employees are the protected class of individuals. (Cal. Labor Code § 1102.5)

- “Employee” is defined as any person employed by an employer, private or public, including, but not limited to, individuals employed by the state or any subdivision thereof, any county or city, including any charter city or county, and any school district, community college district, municipal or public corporation, political subdivision, or the University of California. (Cal. Labor Code § 1106)
WHAT IS A WHISTLEBLOWER?

A “whistleblower” is an employee who discloses information to a government or law enforcement agency, person with authority over the employee, or to another employee, where the employee has reasonable cause to believe that the information discloses:

- A violation of a state or federal statute;
- A violation or noncompliance with a local, state or federal rule or regulation; or
- With reference to employee safety or health, unsafe working conditions or work practices in the employee’s employment or place of employment.
PROTECTIONS AFFORDED TO WHISTLEBLOWERS

- An employer may not make, adopt, or enforce any rule, regulation, or policy preventing an employee from being a whistleblower.

- An employer may not retaliate against a whistleblower.

- An employer may not retaliate against an employee for refusing to participate in an activity that would result in a violation of a state or federal statute.

- An employer may not retaliate against an employee for having previously exercised rights as a whistleblower.
TAXATION
POINTS OF INTERSECTION

- Disclosure or Use of Information by Tax Return Preparers
- Medical Loss Ratio (MLR)
- Reporting Employer Provided Health Coverage in Form W-2
- Net Investment Income Tax
- Additional Medicare Tax
- Minimum Value
- Small Business Health Care Tax Credit
- Health Flexible Spending Arrangements
- Medical Device Excise Tax
POINTS OF INTERSECTION (CONTINUED)

- Health Insurance Premium Tax Credit
- Individual Shared Responsibility Provision
- Health Coverage for Older Children
- Excise Tax on Indoor Tanning Services
- Adoption Credit
- Transitional Reinsurance Program
- Medicare Shared Savings Program
- Qualified Therapeutic Discovery Project Program
POINTS OF INTERSECTION (CONTINUED)

- Group Health Plan Requirements
- Annual Fee on Health Insurance Providers
- Tax-Exempt 501(c)(29) Qualified Nonprofit Health Insurance Issuers
- Additional Requirements for Tax-Exempt Hospitals
- Annual Fee on Branded Prescription Pharmaceuticals
- Employer Shared Responsibility Payment
- Excise Tax on “Cadillac” Plans
- Patient-Centered Outcomes Research Institute
- Retiree Drug Subsidies
TRANSACTIONAL/CORPORATE
INCREASE IN MERGERS/ACQUISITIONS

- In 1999, there were 4,956 hospitals in the United States and 395 in California.

- In 2011, there were 4,973 hospitals in the United States and 345 in California.

- Between 2007 and 2012, 432 hospital mergers and acquisitions included 835 hospitals.
SECURED TRANSACTIONS IN THE NEWS

- September 2014: MidCap Financial acts as sole agent in a $62.5 million senior financing
- May 2014: HFG provides $8 million senior debt
- March 2014: HFG provides $12.5 million senior debt
- March 2014: HFG announces $79 million financing
- December 2013: HFG closes $475 million financing
- October 2012: HFG agents $37 million financing
- August 2012: MidCap acts as joint lead arranger in new $57.5 million senior financing
HEALTH CARE REPS & WARRANTIES

- Compliance with all health care laws
- Focus on privacy policies (HIPAA and HITECH)
- Review health care provider compliance program
- Indemnify against any anomaly in health care industry
- Dependent upon “bonus money” (e.g., QAF program, distressed hospital funding, DSH money)
Craig B. Garner
Garner Health Law Corporation

Craig is an attorney and health care consultant, specializing in issues pertaining to modern American health care and the ways it should be managed in its current climate of reform.

Craig’s law practice focuses on health care mergers and acquisitions, regulatory compliance and counseling for providers. Craig is also an adjunct professor of law at Pepperdine University School of Law, where he teaches courses on Hospital Law and the Affordable Care Act.

Between 2002 and 2011, Craig was the Chief Executive Officer of Coast Plaza Hospital in Norwalk, California. Craig is also a Fellow Designate with the American College of Healthcare Executives and Chair of the State Bar of California, Business Law Section, Health Law Committee.

Additional information can be found at www.garnerhealth.com.
Thank You

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