Litigating Under the Affordable Care Act

STATE BAR OF CALIFORNIA
BUSINESS LAW SECTION
HEALTH LAW AND INSURANCE LAW COMMITTEES

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INTRODUCTION
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.”
The Affordable Care Act

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act into law.

The Health Care and Education Reconciliation Act followed a week later.

Together, this landmark legislation became the Affordable Care Act (“ACA”), also known as Health Care Reform.

March 2014 will be the fourth anniversary of the ACA.
The Supreme Court

Almost 28 months after President Obama signed the ACA into law, the United States Supreme Court upheld its constitutionality, holding:

- The ACA’s individual mandate is constitutional.

- The Medicaid expansion provisions survive, “but the Federal Government is prohibited from penalizing states that choose not to participate by taking away their existing Medicaid funding.”

-- National Federation of Independent Business v. Sebelius
132 S. Ct. 2566 (2012)
Supreme Court (continued)

In ruling that the individual mandate is constitutional, the Court rejected the Commerce Clause and the Necessary and Proper Clause in the Constitution as bases for upholding the mandate.

Instead, the Court found constitutionality of the individual mandate through Congress’s authority to “lay and collect taxes.”

Under its taxing power, Congress can only require “an individual to pay money into the Federal Treasury, no more.”
Chief Justice Roberts’ plurality decision on Medicaid coercion (joined by Justices Breyer and Kagan) held that Congress acted within the scope of the spending power.

However, Chief Justice Roberts limited Medicaid Expansion by denying Congress the ability to threaten existing Medicaid funding. “Though Congress’s power to legislate under the spending power is broad, it does not include surprising participating States with post-acceptance or ‘retroactive’ conditions.”
Chief Justice Roberts argued the Court did “not believe Congress would have wanted the whole Act to fail, simply because some [States] may choose not to participate.”

Justices Scalia, Kennedy, Thomas and Alito disagreed: “We should not accept the Government’s invitation to attempt to solve a constitutional problem by rewriting the Medicaid Expansion so as to allow States that reject it to retain their pre-existing Medicaid funds.”
LITIGATING COVERAGE
Individual Coverage Under the ACA

Although not a seamless transition on January 1, the need to protect individual interests under the ACA may eventually result in litigation over a multitude of issues, including:

- 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
What Is the Individual Mandate?

Under the ACA, the individual mandate requires applicable individuals to maintain minimum essential health insurance coverage (26 U.S.C. § 5000A). The following list includes only a few of the ways in which individuals may qualify:

- Government sponsored programs
- Employer-sponsored plans
- Plans in the individual market (Exchanges, state pools)
- Grandfathered health plans
- Self-funded student coverage
- Foreign health coverage
Violating the Individual Mandate

The penalty for violating the individual mandate (phased in until 2016) is the greater of: (a) $695 or (b) 2.5% of the taxpayer’s household income, not to exceed the value of a “Bronze” plan. Exceptions to compliance include:

- Religious-Based (Health care sharing ministry)
- Not Present in the United States
- Incarceration
- Low Income/Hardship
- Member of Indian Tribe
Enforcement of Penalties

The Federal Government is severely limited in its ability to enforce penalties for violation of the individual mandate.

Among other things, the ACA waives criminal penalties altogether and severely limits the use of liens and levies.

Is this a penalty without much penalty?
Minimum Medical Loss Ratio

The ACA established the Medical Loss Ratio ("MLR") to ensure that issuers of insurance comply as follows:

- **Large Group Market**: An issuer must provide a rebate to enrollees if the issuer has an MLR of less than 85% (subject to adjustments).

- **Small Group and Individual Markets**: An issuer must provide a rebate to enrollees if the issuer has an MLR of less than 80% (also subject to adjustments).
Minimum Medical Loss Ratio (continued)

“[A]n issuer must rebate a pro rata portion of premium revenue if it does not meet an 80 percent MLR for the small group market in a State that has not set a higher MLR. If an issuer has a 75 percent MLR for the coverage it offers in the small group market in a State that has not set a higher MLR, the issuer must rebate 5 percent of the premium paid by or on behalf of the enrollee for the MLR reporting year after subtracting premium and subtracting taxes and fees. . . . In this example, an enrollee may have paid $2,000 in premiums for the MLR reporting year. If the Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue . . . are $150 for a premium of $2,000, then the issuer would subtract $150 from premium revenue, for a base of $1,850 in premium. The enrollee would be entitled to a rebate of 5 percent of $1,850, or $92.50.”
Employer Mandate

Delayed until 2015.
LITIGATING MORALITY
Principles and Public Opinion

- Contraception Mandate
- No Coverage for Undocumented Aliens
- Delay of the Employer Mandate
- Taxes and Rebates
- Health Insurance Exchanges
- Medicaid Expansion
- The Individual Mandate
Immigration

Legal permanent residents may have eligibility restrictions for Medicaid benefits (but can participate in the exchanges).

Unauthorized immigrants are excluded from coverage altogether.

Potential recipients of Medicaid coverage under the expansion are immigrants who will not qualify in 2014:

- Nevada (34%)
- Arizona (31%)
- California (26%)
- Texas (26%)
Contraception Mandate

- The ACA requires coverage without cost-sharing for all FDA approved contraceptive methods.

- All new private health insurance plans offering prescription drug coverage (including all non-group, small and large group and self-funded plans) must comply.

- Religious institutions defined as “houses of worship” are exempt, and certain religiously affiliated organizations may request an accommodation (but insurance companies are still required to cover the cost of contraceptives).
Contraception Mandate (continued)

- The U.S. Supreme Court will hear two Circuit Court decisions on the issue (10th Cir. and 3rd Cir.).

- 89 separate lawsuits have been filed (46 with for-profit entities and 43 with nonprofit entities).

- Courts have granted 33 injunctions and denied 6 on behalf of for-profit plaintiffs, while Courts have granted 6 injunctions and denied 1 on behalf of nonprofit plaintiffs.

- 2 class action lawsuits have been filed.
Contraception Mandate (continued)

- U.S. Supreme Court Justice Sonia Sotomayor granted a temporary exemption on December 31, 2013, to a small group of Catholic nuns that shields them from having to comply with the Contraception Mandate.

- On January 3, 2014, the United States Justice Department responded, defending the controversial provisions of the ACA.

- Recent Changes.
Other Considerations

- Is health care a fundamental right?
- Does the government have the right to establish certain mandates?
- Does the ACA blur the lines between separation of church and state?
- Does EMTALA tip the balance?
LITIGATING INNOVATION
Innovation and Prevention

To reduce patient health care expenditures, the ACA must rely upon innovation and prevention, hoping to improve upon the delivery of health care in the United States. Some examples include:

- Center for Medicare and Medicaid Innovation
- Prevention and Public Health Fund
- Education and Outreach Campaign for Preventative Benefits
- Community Transformation Grants
- Patient-Centered Outcomes Research Institute (PCORI)
Innovation and Prevention  
(continued)

The ACA also established different ways in which providers can deliver medical care, as well as new options for providers to collaborate:

- Accountable Care Organizations
- Bundled Payments for Care Improvement Initiative
- Federally Qualified Health Center (FQHC)
- Patient-Centered Medical Homes
ACO Litigation

An ACO is a shared savings program that promotes accountability for a patient population, coordinates items and services under Medicare Parts A and B, and encourages investment in infrastructure and redesigned care processes.

- Approximately 350 ACOs by the end of 2013
- Quality care measures
- Focus on at-risk populations
- Compliance responsibilities
- IRS exceptions (for non-profit entities)
- Corporate practice of medicine issues
- Stark exceptions
Bundled Payments for Care Improvement Initiative

Under this initiative, organizations will enter into payment arrangements that include financial and performance accountability for episodes of care.

- **Model 1**: Retrospective Acute Care Hospital Stay Only
- **Model 2**: Retrospective Acute Care Stay *plus* Post-Acute
- **Model 3**: Retrospective Post-Acute Care Only
- **Model 4**: Acute Care Hospital Stay Only
Patient-Centered Medical Homes Litigation

The patient-centered medical home is a way of organizing primary care that emphasizes care coordination and communication to transform primary care into “what patients want it to be.”

- Comprehensive Team of Care Providers
- Patient Centered
- Coordinated Care During Transitions
- Accessible Services
- Quality and Safety

*What does a patient want it to be?*
LITIGATING MEDICARE
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 within 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 in the Medicare Appeal Process

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 (MAC))
- Reconsideration by a Qualified Independent Contractor (QIC)
- Hearings before an Administrative Law Judge (ALJ) 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).
Physician Owned Hospitals

Federal regulations include a “whole hospital” exception to the Stark Laws. This particular safe harbor requires that the referring physician/owner: (1) have a financial interest in the whole hospital, and not just a specific part; (2) be authorized to perform services at the hospital; and (3) be expected to actually perform the agreed upon services.

Section 6001 of the ACA added new regulatory restrictions and requirements for physician-owned hospitals, and also eliminated the safe harbor for hospitals that did not qualify by the end of 2010.
Physician Owned Hospitals (continued)

Constitutional challenges to Section 6001 have thus far been unsuccessful. In one Texas District Court case, hospital providers lost a Constitutional challenge on the basis that Section 6001 violated the Fifth Amendment. The District Court granted summary judgment in favor of the Federal Government, concluding that the ACA makes the intent of Congress clear.

The Court also noted, however, that the hospital providers may have the better reasoned argument and “wiser legislative approach.” Nevertheless, the Court found no Constitutional concerns with Section 6001. *Physician Hospitals of America v. Sebelius*, 781 F. Supp. 2d 431 (E.D. Tex. 2011).
Physician Owned Hospitals  (continued)

On appeal, the Fifth Circuit vacated and *dismissed* the entire lawsuit for lack of subject-matter jurisdiction, holding that the Medicare Act imposes specific restrictions on any challenges, requiring “virtually all legal attacks” be brought through HHS.

The Court held that the hospital providers must first comply with 42 U.S.C. § 1395ii and submit the dispute to HHS, and only after HHS reaches a final decision may the party “obtain review of such decision by a civil action.” *Physician Hospitals of America v. Sebelius*, 691 F.3d 649 (5th Cir. 2012).
Litigating Performance Based Reimbursement

The ACA introduced a fundamental change to the Medicare system, although its implementation has just begun and will continue over the next several years. If \textit{efficiency} had in the past defined Medicare’s reimbursement model, \textit{performance} now defines this most recent evolution.

- Hospital/Physician Value Based Purchasing Programs
- Hospital Readmissions Reduction Program
- Hospital Acquired Conditions
- Hospital Associates Infections
TAXES AND REFORM
Litigating the Points of Intersection

The ACA has become inextricably connected to the laws of federal and state taxation, all of which may result in future litigation. Some points of intersection include:

- Disclosure or Use of Information by Tax Return Preparers
- Medical Loss Ratio (MLR) (discussed above)
- Reporting Employer Provided Health Coverage in Form W-2
- Net Investment Income Tax (3.8% tax as of 2013)
- Additional Requirements for Tax-Exempt Hospitals
- Minimum Value
- Tax-Exempt 501(c)(29) Qualified Nonprofit Health Insurance Issuers
Additional Points of Intersection

- Health Flexible Spending Arrangements
- Medical Device Excise Tax (2.3% tax as of 2010)
- Health Insurance Premium Tax Credit
- Individual Shared Responsibility Provision
- Health Coverage for Older Children
- Excise Tax on Indoor Tanning Salons (10% tax as of 2010)
- Adoption Credit
- Transitional Reinsurance Program
- Medicare Shared Savings Program
- Small Business Health Care Tax Credit
And More Points of Intersection

- Therapeutic Discovery Project Program
- Group Health Plan Requirements
- Annual Fee on Health Insurance Providers
- Additional Medicare Tax (0.9% tax as of 2013)
- Annual Fee on Branded Prescription Pharmaceuticals
- Employer Shared Responsibility Payment
- Excise Tax on “Cadillac” Plans
- Patient-Centered Outcomes Research Institute
- Retiree Drug Subsidies
PROCEED WITH CAUTION
The Absence of Any Recall

Although in place before the ACA, the Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Clinical and Economic Health (HITECH) have evolved.

Any “covered” entity that maintains “unsecured” protected health information and “discovers” a “breach of such information” must notify each individual whose PHI “has been, or is reasonably believed by the covered entity to have been, accessed, acquired, or disclosed as a result of such breach.”
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
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.
The Genetic Information Nondiscrimination Act of 2008

“GINA” is the leading federal protection of genetic information, but it only prohibits genetic discrimination in health insurance and employment.

GINA does not regulate access, security or disclosure of genetic or whole genome sequence information across all potential users, nor does it protect against discrimination in other contexts. State laws vary for similar protections.

Genetic information protections are only briefly mentioned in the Affordable Care Act.
FRAUD AND ABUSE
Medicare Fraud and Abuse

- **The Social Security Amendments of 1972**: Regulating Medicare provider fraud and abuse, as well as over utilization and unnecessary referrals.

- **Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977**: Expanding the scope of prohibited conduct under Medicare to include practically any remuneration for a physician from a referral.

- **Civil Monetary Penalties Law of 1981**: Authorizing the Federal Government to assess fines as well as enforce program exclusions.
And More…


- Ethics in Patient Referral Act of 1989 (the "Stark Laws"): Targeting physician referrals for clinical services to an entity in which the physician has a financial interest.

- Omnibus Budget Reconciliation Act of 1993 ("Stark II") and the 2007 modifications to Stark II (informally known as Stark III).
And More…

- **The Fraud Enforcement and Recovery Act of 2009**: Expanding the reverse false claim provision significantly so that it now prohibits “knowingly conceal[ing] or knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay” the United States.

- **Section 6402 of the ACA**: Establishing a new requirement for: “Reporting and Returning of Overpayments” within 60 days of identifying the overpayment.
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
Craig B. Garner

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, a Member of the State Bar of California, Business Law Section, Health Law Committee and a Vice Chair of the Healthcare Reform Educational Task Force of the American Health Lawyers Association.

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Olivier Taillieu is a trial lawyer specializing in complex civil litigation. Olivier's cases have ranged from representing medical device manufacturers to pharmaceutical companies. His expertise also extends to cases involving unfair competition, unfair business practices, copyright disputes, class actions, entertainment, and breach of contract. Prior to founding the Taillieu Law Firm, Olivier co-founded and managed the firm Zuber & Taillieu LLP (now Zuber, Lawler & Del Duca LLP). Prior to that Olivier was an associate at O’Melveny & Myers LLP.


Olivier is currently an editor on the Trademark Reporter. He also sits on the Board of Governors of the Association of Business Trial Lawyers and heads its Public Service committee. Additionally, Olivier is an active member of the Corporate Counsel Committee of the Litigation Section of the American Bar Association where he co-chairs the publication subcommittee.
Thank You