



American Bar Association Health Law Section

**14th Annual Conference on
Emerging Issues
in
Healthcare Law**

February 20-23, 2013

Miami Marriott Biscayne Bay

Program Co-Sponsors:

American Bar Association's

Section of Dispute Resolution

Section of Science & Technology Law

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SCHEDULE AT-A-GLANCE

WEDNESDAY, FEBRUARY 20, 2013

8:30 am – 5:00 pm	Registration
9:00 am – 12:30 pm	Breast Cancer Legal Advocacy Workshop <i>Sponsored by: Breast Cancer Task Force</i>
10:00 am – 12:00 pm	Social Media for Health Law Attorneys <i>Sponsored by: ABA Law Practice Management Section</i>
1:00 pm – 4:00 pm	So You're a Healthcare Attorney, Now What? The Practical Realities for New Healthcare Attorneys Taught Through Case Studies on Everyday Scenarios <i>Fundamentals Session</i>
1:00 pm – 5:00 pm	Attorney as Conflict Coach: Expanding the Role and Skills of Health Lawyers in a Climate of Rapid Change <i>Sponsored by: Conflict Management Task Force</i>
3:00 pm – 5:00 pm	ABA Health Law Section Interest Group Leadership Meeting
5:00 pm – 6:00 pm	The Affordable Care Act: Reducing Health Inequities in Underserved Communities Roundtable Discussion
6:00 pm – 8:00 pm	Networking Reception <i>Celebrating Diversity, Young Lawyers and Law Students</i>

THURSDAY, FEBRUARY 21, 2013

8:00 am – 5:00 pm	Registration
8:00 am – 9:00 am	Continental Breakfast
9:00 am – 9:30 am	Welcome to EMI! Opening Remarks From the Planning Committee Co-Chairs
9:30 am – 11:00 am	Looking into the Crystal Ball-The State of Health Care Post-Reform and Post-Election
11:15 am – 12:30 pm	Why We Litigate: Government and In-House Counsel Analysis of the Underlying Decisions That Motivate Their Organizations to Investigate and Litigate <i>Sponsored by: Litigation and Risk Management Interest Group</i>
11:15 am – 12:30 pm	Conflict Resolution in the Hospital Board/Medical Staff Context <i>Sponsored by: Physician Issues Interest Group</i>
11:15 am – 12:30 pm	Everything Your Clients Want You To Know About Tax Issues for ACOs and Clinical Integration Networks <i>Sponsored by: Tax & Accounting Interest Group</i>
12:45 pm – 2:00 pm	Interest Group Luncheons
2:15 pm – 3:45 pm	Emerging Trends in Enforcement Update
3:45 pm – 4:45 pm	Honoring Your Ethical Obligations While Defending Health Care Providers and Entities During an Investigation
5:00 pm – 6:15 pm	What's for Dinner? Food Regulation and Public Health <i>Sponsored by: Public Health & Policy Interest Group</i>
5:00 pm – 6:15 pm	Current Topics and Emerging Trends in Managed Care Litigation <i>Sponsored by: Managed Care & Insurance Interest Group</i>

SCHEDULE AT-A-GLANCE

5:00 pm – 6:15 pm	Urgent Care Centers: The Legal and Practical Issues for Development <i>Sponsored by: Healthcare Facility Operations Interest Group</i>
6:30 pm – 9:00 pm	Welcome Reception <i>Honoring our faculty and planning committee members</i>

FRIDAY, FEBRUARY 22, 2013

8:00 am – 5:00 pm	Registration
8:00 am – 9:00 am	Continental Breakfast
9:00 am – 9:15 am	State of the Section Address
9:15 am – 10:45 am	Our Nation's Veterans' Courts and Criminal Justice System: A Public Health Policy Approach <i>Sponsored by: Substance Use Disorders Task Force</i>
11:00 am – 12:15 pm	Recent Trends in Academic Medical Center Acquisitions and Affiliations <i>Sponsored by: Business & Transactions Interest Group</i>
11:00 am – 12:15 pm	Fraud and Compliance Issues for ACOs and Integrated Health Systems <i>Sponsored by: Healthcare Fraud & Compliance Interest Group</i>
11:00 am – 12:15 pm	Cells as Drugs: FDA Regulation of Your Drugs <i>Sponsored by: Medical Research, Biotechnology & Clinical Ethical Issues</i>
12:30 pm – 1:45 pm	Interest Group Luncheons
2:00 pm – 3:30 pm	Emerging Trends in Physician Alignment Strategies: Consolidation, Joint Ventures and Payment Structures
2:15 pm – 3:30 pm	Law Student Meet and Greet
3:45 pm – 5:00 pm	Helping Employers With Compliance in a Post-PPACA World <i>Sponsored by: Employee Benefits & Executive Compensation Interest Group</i>
3:45 pm – 5:00 pm	Observation Status: Caught Between a Rock and a Hard Place? <i>Sponsored by: Payment & Reimbursement Interest Group</i>
3:45 pm – 5:00 pm	Once More unto the Breach! Security Rule Compliance, Risk Assessments, Risk Mitigation Strategies, and What to Do When Things Go Wrong <i>Sponsored by: eHealth, Privacy & Security Interest Group</i>

SATURDAY, FEBRUARY 23, 2013

8:00 am – 11:30 am	HLS Council Meeting
12:15 pm – 5:30 pm	Margarita Cup Golf Outing
12:15 pm – 5:30 pm	Taste of South Beach Culinary Tour and Boat Tour
6:00 pm – 9:00 pm	Chair's Reception and Margarita Cup Awards Ceremony

SUNDAY, FEBRUARY 24, 2013

8:00 am – 11:00 am	Council Meeting
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PROGRAM AGENDA

WEDNESDAY, 2/20/13

9:00-12:30

Breast Cancer Legal Advocacy Workshop

Sponsored by: Breast Cancer Task Force

Cancer patients face a variety of legal problems related to their illness, including coverage and payment for treatment as well as employment issues. This seminar is geared toward attorneys who do not ordinarily handle cases of this type. In addition to making you aware of relevant laws, practices, and procedures you will be equipped with basic information you will need to start assisting breast cancer patients or members of their support system with legal problems they may face.

Moderator:

George Wickhorst, Esq., Young Berman Karpf & Gonzalez, P.A., Miami, FL

Speakers:

M. Barbara Amaro, Esq., M. Barbara Amaro, Esq., Miami, FL

Cynthia A. Everett, Esq., Cynthia A. Everett, PA, Miami, FL

Laura Riley, Esq., Cancer Legal Resource Center, Disability Rights Legal Center, Los Angeles, CA

Christopher S. Sears, Esq., Ice Miller LLP, Indianapolis, IN

Michael Cusnir, MD, Mt. Sinai Comprehensive Cancer, Miami Beach, FL, *invited*

10:00-12:00

Social Media for Health Law Attorneys

Sponsored by: ABA Law Practice Management Section

The economy is still fragile and there are too many lawyers competing for a shrinking pool of clients. Social media can help bring in clients, but attorneys are hopelessly confused about how to use Facebook, LinkedIn, Twitter and the other major social media players. Yes, social media can be a gold mine - but it can also be an ethical minefield. In addition, social media can be a valuable tool in the healthcare industry, but healthcare providers, and their lawyers, must be able to quickly identify repercussions of such public forms of communication and prevent inadvertent disclosures. Our experts will show you how to use (and advise on) social media ethically and effectively by addressing:

- Should you use social media or avoid it?
- Which social media platforms are most effective for lawyers?

- Your plates are full - how can you find time to use social media?
- What are the best tips for managing social media - is there a single "dashboard?"
- How you can measure the success of your social media efforts?
- What are the ethical issues when using social media?
- What considerations do healthcare lawyers need to pay attention to when advising clients regarding social media?
- What are the components of a good law firm and healthcare entity social media policy?

Speakers:

Debbie Foster, Affinity Consulting Group, Largo, FL

Marc M. Meyer, RN, JD, Law Office of Marc Meyer, PLLC, Magnolia, TX

1:00-4:00

So You're a Healthcare Attorney, What Now? The Practical Realities for New Healthcare Attorneys Taught through Case Studies on Everyday Scenarios

Attorneys new to the practice of health law are often overwhelmed by the breadth and complexity of the industry, the regulatory framework in which it operates, and the resulting complex legal and business issues that arise when counseling clients. The most valuable training comes from being immersed in actual projects of all sizes for clients seeking our advice on the related legal and business decisions. This program will replicate that on-the-job training (to the extent possible in a very short timeframe). Participants will have the opportunity to learn the fundamentals of the practice and the key underlying laws (e.g. Anti-Kickback Statute, Stark Law, False Claims Act, HIPAA) through three day-to-day scenarios focusing on the regulatory, enforcement, and transactional contexts that may be encountered frequently by new healthcare attorneys.

Speakers:

Jonathan Anderman, Holland & Knight, Boston, MA

Arianne Callender, Morgan, Lewis & Bockius LLP, Washington, DC

Matt Fisher, Mirick O'Connell, Worcester, MA

Felicia E. Heimer, Senior Counsel, Office of Counsel to the Inspector General, U.S. Department of Health and Human Services, Miami Lakes, FL

PROGRAM AGENDA

1:00-5:00

Attorney as Conflict Coach: Expanding the Role and Skills of Health Lawyers in a Climate of Rapid Change

Sponsored by: Conflict Management Task Force

Delivering health care in a climate of rapid change demands new forms of collaboration and problem solving by health care clients, and thus the job of health lawyers requires expansion of approaches for effective problem solving and conflict engagement. This interactive workshop is designed to help attorneys expand their approaches and skills to include collaborative problem-solving, expanded communication skills, and conflict coaching techniques in order to better serve clients who struggle to stay ahead of the change curve and to support the well-being of attorneys who feel the impact of working at the sharp end of change.

Session Highlights:

- Overview of the mandates for managing conflict and fostering collaboration within and among health care organizations;
- Framework for collaborative problem-solving with clients and colleagues;
- Skills and tools that enhance attorneys' effectiveness with clients to achieve collaboration and fulfill professional standards as counselors at law;
- Conflict competence as an adjunct to ADR
- Effective spot-coaching techniques that can be incorporated into interactions with clients, regulators, and opposing counsel to foster collaboration and address conflict

Speakers:

Jeanne F. Franklin, Esq., Mediator, Franklin Solutions, Arlington, VA

Debra Gerardi, President & Chief Creative Officer, EHCCO, LLC, Half Moon Bay, CA

Charity Scott, Professor of Law and Director, Center for Law, Health & Society, Georgia State University College of Law, Atlanta, GA

3:00-5:00

Interest Group Leadership Meeting

5:00-6:00

The Affordable Care Act: Reducing Health Inequities in Underserved Communities Roundtable Discussion

This year, the ABA Health Law Section's Coordinating Committee on Diversity and Proskauer Rose LLP are proud to present a Roundtable discussion of academics, practicing attorneys and community leaders entitled, The Affordable Care

Act: Reducing Health Inequities in Underserved Communities. Our Roundtable panel will address the current state of health care for persons of color, those who are disproportionately uninsured or underinsured and those who, for a variety of factors, face greater barriers to receiving high quality care (even when insured). In doing so, the panel will examine whether the Affordable Care Act can help break some of these barriers and improve access to health care coverage and improvement in health and wellbeing in these communities. Audience participation in the discussion will be encouraged.

Our esteemed panel includes:

Charlton Copeland, Associate Professor of Law, University of Miami School of Law

JoNel Newman, Associate Professor of Clinical Legal Education, University of Miami School of Law

Moderator:

Denise E. Hanna, Partner, Locke Lord Strategies, Washington, DC

The Roundtable discussion will be held from 5:00pm – 6:00pm in the Watson room and is FREE and OPEN to all who wish to attend, including law students and is not limited to Conference attendees.

A Diversity Reception will immediately follow the Roundtable in the Bayside Reception Room next door. The Diversity Reception will present a wonderful networking opportunity for attorneys, policymakers and law students interested in various aspects of healthcare law. The Reception also affords the ABA Health Law Section an opportunity to continue to build bridges and strengthen relationships with attorneys and law students having a diversity of backgrounds.

All are welcome and encouraged to attend the Roundtable and Diversity Reception which follows. The Coordinating Committee on Diversity would like to thank Proskauer Rose LLP for its generous support and sponsorship of the roundtable and Diversity Reception.

6:00-8:00

Networking Reception

Celebrating Diversity, Young Lawyers and Law Students

All registered conference attendees are invited to attend the reception to catch up with old friends and meet new ones! We will offer a meet and greet with our Diversity speakers. Strolling dinner stations and cocktails will be open during the reception.

New this year! Law students and Young Lawyers are invited to mix and mingle in the reserved VIP lounge inside the reception.



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THURSDAY, 2/21/13

9:00-9:30

Welcome to EMI! Opening Remarks

Speakers:

David Douglass, Chair, American Bar Association Health Law Section

Denise Glass, Co-Chair, Emerging Issues in Healthcare Law Conference Planning Committee

Lisa D. Taylor, Co-Chair, Emerging Issues in Healthcare Law Conference Planning Committee

9:30-11:00

Looking into the Crystal Ball-The State of Health Care Post-Reform and Post-Election

With the 2012 Presidential election behind us, PPACA is now the law of land. This panel will discuss how payors and providers are reacting to and planning for the changes brought about by PPACA.

In a highly-interactive session, the panel will explore:

- An overview of the provisions of PPACA
- Bundled payments, medical homes and ACOs
- How providers are preparing for the vast numbers of newly insured patients
- How payors are planning for full implementation in 2014, including the elimination of pre-existing conditions waiting periods
- Managing the newly-insured population—an ounce of prevention worth a pound of cure

Moderator:

Beth Connor Guest, Waller Lansden Dortch & Davis, Nashville, TN

Speakers:

Eduardo J. Sanchez, MD, MPH, FFAFP, Vice President & Chief Medical Officer, Blue Cross Blue Shield of Texas, Richardson, TX

Howard T. Wall III, Executive Vice President & Chief Administrative Officer, RegionalCare Hospital Partners, Brentwood, TN

James S. Wendel, MD, President, Obstetrics and Gynecology, The Christ Hospital Clinically Integrated Network

Concurrent Sessions

11:15-12:30

Why We Litigate: Government and In-House Counsel Analysis of the Underlying Decisions That Motivate Their Organizations to Investigate and Litigate

Sponsored by: Litigation and Risk Management Interest Group

The government has limited resources. So do health care companies. As a result they cannot investigate and/or litigate every single potential matter or case that arises. Sometimes they pass on cases or settle early. Although the absence of unlimited resources causes these entities to make such decisions the reasons for the decisions are far more complicated. Additionally, too often parties in healthcare litigation fail to discuss the underlying motives behind their decisions. This panel of government and in-house counsel will discuss their motivations and helpfully prod further conversations that will reduce the far-too-frequent hostile relations between litigants.

Moderator:

David T. Fischer, Shook Hardy & Bacon, Washington, DC

Speakers:

Mitchell S.Y. Cohen, Vice President and General Counsel, CEP American / MedAmerica, Inc., Emeryville, CA

John E. Steiner, Jr., Chief Compliance Officer, Cancer Treatment Centers of America, Schaumburg, IL

Ryan Stumphauzer, O'Quinn Stumphauzer P.L., Miami, FL

11:15-12:30

Conflict Resolution in the Hospital Board/Medical Staff Context

Sponsored by: Physician Issues Interest Group

This panel will present a case study for conflict resolution involving medical staff leaders, governing boards and hospital administrators, address the different stakeholders and possible solutions. Issues that surface during medical staff bylaws negotiations will be featured. Joint Commission standards, relevant statutes and regulations, and other rules of the game will be presented by opponents/collaborators/veterans of a recent successful conflict resolution process.

Moderator:

Julian L. Rivera, Brown McCarroll LLP, Austin, TX

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Speakers:

Bernard Duco, Chief Legal Counsel, Memorial Herman Healthcare, Houston TX, *invited*

Elizabeth Snelson, Legal Counsel for the Medical Staff PLLC, St. Paul, MN, *invited*

11:15-12:30

Everything Your Clients Want You to Know About Tax Issues for ACOs and Clinical Integration Networks

Sponsored by: Tax & Accounting Interest Group

This expert panel will present a soup-to-nuts overview of the tax issues to be considered when structuring and operating an ACO or other clinical integration network. Topics to be covered include choice of entity, funding, potential state tax issues, taxation of incentive payments and unrelated business income.

Moderator:

Lauren Mack, Polsinelli Shughart PC, Chicago, IL

Speaker:

Richard T. Frazier, Esq., Saul Ewing LLP, Philadelphia, PA

12:45-2:00

Interest Group and Task Force Luncheons

- Employee Benefits & Executive Compensation
- Healthcare Fraud & Compliance
- Managed Care & Insurance
- Medical Research, Biotechnology & Clinical Ethical Issues
- Payment & Reimbursement
- Public Health & Policy
- Substance Use Disorders
- Nursing & Allied Healthcare Professionals

2:15-3:45

Emerging Trends in Enforcement

This session will discuss recent trends in federal criminal, civil, and administrative healthcare fraud enforcement. The panel includes both government and defense counsel with years of experience litigating and negotiating health care settlements. Topics will include False Claims Act cases, criminal prosecutions, and administrative actions.

Moderator:

Gabriel L. Imperato, Esq., Broad and Cassel, Fort Lauderdale, FL

Speakers:

Gregory E. Demske, Chief Counsel to the Inspector General, U.S. Department of Health and Human Services, Washington, DC

Jane W. Moscovitz, Moscovitz & Moscovitz, P.A., Miami, FL

Joan Silverstein, Chief, Economic & Environmental Crimes Section, U.S. Attorney's Office, Southern District of Florida, Miami, FL

3:45-4:45

Ethics: Honoring Your Ethical Obligations While Defending Health Care Providers and Entities During an Investigation

A lawyer representing a client under investigation must be mindful of his or her ethical duties. Among the questions that arise are the ability of a lawyer to represent multiple parties, the duties a lawyer representing an entity under investigation has to the employees and other constituents of that entity, and the obligations imposed by non-public investigations (such as a sealed Qui Tam investigation) on lawyers seeking to vigorously defend their clients. This panel will explore these questions and other issues relating to counsel's ethical duties in connection with defending health care clients under investigation.

Moderator:

Lisa D. Taylor, Inglesino Pearlman Wyciskala & Taylor LLC, Parsippany, NJ

Speakers:

Andrew J. Demetriou, Director, Berkeley Research Group, LLC, Los Angeles, CA

Robert T. Rhoad, Crowell & Moring LLP, Washington DC

Concurrent Sessions

5:00-6:15

What's for Dinner? Food Regulation and Public Health

Sponsored by: Public Health & Policy Interest Group

Food policy and regulation can impact the public's access to safe food and prevent diet-related diseases. In 2011, the President signed the Food Safety Modernization Act, the most sweeping reform of the food safety laws in over 70 years. Cities are pursuing innovative food policy strategies designed to get healthy foods into communities and industry is undertaking efforts aimed at informing consumers and combatting obesity. This panel will be a discussion among experts from the federal government, local public health departments, industry, and clinicians about the different policies being pursued by various stakeholders to tackle these issues, and the ability of food regulation and policy to achieve these goals.

Speakers:

LTC Bonnie B. Archer, Chief, Nutrition Care Division, Dwight D. Eisenhower Army Medical Center, Fort Gordon, GA



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Joshua Eizen, Associate Chief Counsel for Enforcement, Food and Drug Administration, Silver Spring, MD

Thomas Merrill, General Counsel, New York City Department of Health and Mental Hygiene, New York, NY

5:00-6:15

Current Topics and Emerging Trends in Managed Care Litigation

Sponsored by: Managed Care & Insurance Interest Group

This program will provide an overview of emerging issues impacting the managed care litigation arena, covering topics such as ERISA litigation, mental health parity, autism litigation, and recent payor litigation over providers' discount practices. The experienced panel will also address potential litigation risks arising from PPACA, covering subjects such as essential health benefits, medical loss ratio, and provider non-discrimination. Audience members will acquire knowledge of how to both spot and address potential litigation risks associated with these topics.

Moderator:

Josephine Nelson Harriott, Miller & Chevalier Chartered, Washington, DC

Speakers:

Andrew J. Hefty, Crowell & Moring LLP, San Francisco, CA

Leigh Anne Hodge, Bradley Arant Boult Cummings, Birmingham, AL

5:00-6:15

Urgent Care Centers: The Legal and Practical Issues for Development

Sponsored by: Healthcare Facility Operations Interest Group

This session will discuss the legal and practical issues that need to be addressed in the development of an urgent care center. It will further address the use of the urgent care center as a model for the integration of physician practices with hospitals or healthcare systems. More specifically, the speakers will focus on the state and federal laws that need to be considered as part of any project to develop an urgent care center, whether as a stand-alone entity or in conjunction with a hospital or healthcare system. They will also address the due diligence work that is necessary as a part of the development process, the various internal policies that such centers need for their operations once they are established, and the differentiation between urgent care centers and

other similar models of care such as retail clinics and freestanding emergency departments.

Moderator:

Neil W. Kunkel, SVP & General Counsel, Capella Healthcare, Franklin, TN

Speakers:

Renee Lohman, Chief Executive Officer, CareWell Urgent Care, Quincy, MA

Steven R. Smith, Ober|Kaler, Washington, DC

6:30-9:00

Welcome Reception

Honoring our faculty and planning committee members

All registered conference attendees are invited to attend the best networking reception in the industry! This event receives rave reviews every year, and it's one you don't want to miss. Cocktails and strolling dinner stations will be open during the posted reception hours.

FRIDAY, 2/22/13

9:00-9:15

State of the Section Address

Speaker:

David Douglass, Chair, American Bar Association, Health Law Section

9:15-10:45

Our Nation's Veterans' Courts and Criminal Justice System: A Public Health Policy Approach

Sponsored by: Task Force on Substance Use Disorders

The program will explore our nation's approach to dealing with behavioral manifestations of what are essentially biological/brain/physiological conditions; discuss the vital scientific/medical piece and the integration of behavioral health care into mainstream medicine, as well as the cost-savings associated with this approach; examine our criminal justice/veterans court system and the handling of veterans and others suffering from mental health and substance use disorders in that system; and discuss the application of a public health policy approach to veterans and others in the criminal justice system, which would provide remedial, long-term solutions. Patrick Kennedy will present developments of his One Mind for Research Foundation, and related issues. Dr. Tom McLellan will present the science/medical integration/cost-savings piece. Chief Judge Melanie May will present the criminal justice/veterans/drug and problem solving court segment of the program. The

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program will be moderated by former ABA President and mayor of Detroit, Dennis Archer.

Moderator:

Dennis W. Archer, Chairman & CEO, Dennis W. Archer PLLC, Detroit, MI

Speakers:

Former Congressman Patrick Kennedy, Co-Founder, One Mind for Research, Island Heights, NJ

Melanie G. May, Chief Judge, Fourth District Court of Appeal, West Palm Beach, FL

A. Thomas McLellan, PhD, Chief Executive Officer, Treatment Research Institute, Philadelphia, PA

Concurrent Sessions

11:00-12:15

Recent Trends in Academic Medical Center Acquisitions and Affiliations

Sponsored by: Business & Transactions Interest Group

Academic Medical Centers (AMCs) have been taking a more active role in hospital mergers and acquisitions, looking to expand through both traditional acquisitions as well as affiliation agreements with community hospitals and other providers both in their markets and outside through regional networks. An experienced panel of experts will explore transaction structures used by AMCs in expanding their healthcare delivery platforms and the speakers will address their experiences.

The panel will address:

- Models of affiliation
- Unique operational issues
- Cultural considerations
- Governance—how to address the needs of diverse stakeholders

Speakers:

Paul D. Gilbert, Executive Vice President & Chief Legal Officer, LifePoint Hospitals, Brentwood, TN

Brent L. Henry, Vice President & General Counsel, Partners Healthcare System, Boston, MA

Jan Murray, K&L Gates, LLP, Boston, MA

11:00-12:15

Fraud and Compliance Issues for ACOs and Integrated Health Systems

Sponsored by: Healthcare Fraud & Compliance Interest Group

Given that health care reform has inspired a rising tide of institutional, individual, and group-based health care providers entering into complex collaborative relationships, fraud and abuse concerns have become more important to analyze in the context of integrated delivery arrangements, clinically-integrated networks, and ACOs.

Topics to be covered include:

- The requirements to qualify as an ACO under the MSSP and how they are distinguished from other integrated delivery arrangements
- The fraud and abuse provisions relevant to ACOs and other integrated delivery arrangements including physician self-referrals, kickbacks, beneficiary inducements, and gain-sharing arrangements.
- Relevant government guidance including MSSP OIG Waivers (Interim Final Rule), Compliance Program Guidances.
- Hypotheticals and potential ways to structure ACOs and other integrated delivery arrangements to comply with legal requirements including implementing a compliance reporting framework throughout the organization; and characteristics of effective compliance with the OIG waivers for ACOs preparing to apply for, or participating in, the Medicare Shared Savings Program.

Moderator:

Thomas D. Anthony, Chair, Health Care Industry Practice, Frost Brown Todd, LLC, Cincinnati, OH

Speakers:

Vicki L. Robinson, Senior Counselor for Policy, Office of the Inspector General, Department of Health and Human Services, Washington, DC

Stephanie D. Willis, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, PC, Washington, DC

11:00-12:15

Cells as Drugs: FDA Regulation of Your Drugs

Sponsored by: Medical Research, Biotechnology & Clinical Ethical Issues

A recent decision in the case *US v. Regenerative Sciences, LLC* by the United States District Court holding that adult stem cells are drugs has created considerable controversy as to the jurisdiction of the FDA and its impact on innovation for cell-based therapies.

Efforts are underway in some states to circumvent the ability of the FDA to regulate these sorts of activities by promoting legislation that defines the activities involved in cell-based therapies as medical practice, thereby raising issues of preemption, among others. This session will examine the Regenerative Sciences decision, the legal basis for allowing the FDA to regulate cells as drugs, whether there is a need for further regulation, and whether regulation can be accomplished within the current FDA framework. The speakers, who come from various backgrounds and points of view in this evolving debate, will explore alternative approaches that are intended to protect patients but allow innovation.



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Moderator:

S. Chris Pappas MD, JD, The Woodlands, TX

Speakers:

Torrey Cope, Sidley Austin LLP, Washington, DC

Bambi Grilley, RPh, RAC, CIP, CCRC, CCRP,

Director, Clinical Protocol Research and Regulatory Affairs; Texas Children's Cancer Center and Assistant Professor of Pediatrics, Baylor College of Medicine, Houston, TX

12:30-1:45

Interest Group and Task Force Luncheons

- Business & Transactions
- eHealth, Privacy & Security
- Healthcare Facility Operations
- Healthcare Litigation & Risk Management
- Long Term Care
- Physician Issues
- Tax & Accounting

2:00-3:30

Emerging Trends in Physician Alignment Strategies: Consolidation, Joint Ventures and Payment Structures

Because of the growth in physician alignment strategies, counsel for health systems across the country are often asked to make quick assessments of a multitude of physician service agreements. These agreements cover a range of strategies, such as complex co-management agreements and simple medical directorships. A number of factors drive this alignment growth, including physicians seeking relief from reimbursement pressures and information technology costs, and hospitals requiring physicians' clinical expertise as their reimbursement becomes tied to quality. These arrangements, no matter what their structure, require legal review and, if appropriate, approval of stated compensation. This session will discuss trends in physician alignment strategies along with important regulatory and valuation guidelines associated with various strategies.

Moderator:

Lisa M. Ohrin, Vice President and Associate General Counsel, Health Management Associates, Inc., Naples, Florida

Speakers:

D. Louis Glaser, Katten Muchin Rosenman, Chicago, Illinois

Jen Johnson, CFA, VMG Health, Dallas, Texas

2:15-3:30

Law Student Meet and Greet

Concurrent Sessions

3:45-5:00

Helping Employers with Compliance in a Post-PPACA World

Sponsored by: Employee Benefits & Executive Compensation

Compliance with the various PPACA provisions set to become effective in the 2013-2014 years is a hot topic for employers. PPACA could fundamentally alter the way in which employers provide health benefits to their employers and may result in significant penalties to employers who do not provide health insurance coverage. This breakout will outline employer action items required for the 2013-2014 years such as: comparative effectiveness fees; flexible spending account limits; several employer notice requirements; new contraception coverage mandates; summaries of benefits and coverage; and other requirements. The panel will discuss what the employer will be required to do for each of these provisions and what effect these provisions may have on the employer administratively and financially. Additionally, the session will cover how employers are bracing for the health care reform provisions, the employer mandate, employer penalties, and what the insurance market is anticipating or doing in preparation for the potential market changes resulting from the Exchanges.

Speakers:

Lisa R. Nelson, Esq., Director, Compliance & Regulatory Affairs, Barney & Barney LLC, San Diego, CA

Christopher S. Sears, Ice Miller LLP, Indianapolis, IN

3:45-5:00

Observation Status: Caught Between a Rock and a Hard Place?

Sponsored by: Payment & Reimbursement Interest Group

Physicians working in hospitals must decide whether to admit a patient or continue to treat him or her as an outpatient, observing the patient's status. Under Medicare's current policies, this decision, which should be guided by medical considerations, can have financial consequences. Medicare contractors are increasingly denying hospital payment for admissions that result in relatively short inpatient stays, often concluding that the patient needed observation care only. In such cases, however, Medicare rules do not allow a hospital to re-categorize the patient post-discharge as

PROGRAM AGENDA

an outpatient, and hospitals cannot re-bill for the full range of services that indisputably were provided, including observation services. On the other hand, if a physician continues to place a patient in observation status, this decision could affect whether Medicare will cover the beneficiary's subsequent skilled nursing facility care. Also, Medicare payments may not adequately cover a hospital's resources expended for "observation care."

This program will cover many legal issues raised by this problem, including:

- The Medicare coverage and payment rules regarding inpatient versus outpatient (observation) status, guidelines for inpatient admission criteria, the weight to be granted to admitting-physician decisions, and Medicare policy regarding pre-discharge changes to a patient's status and re-billing for outpatient services following a denial for inpatient services
- The Centers for Medicare & Medicaid Services' (CMS) Medicare Part A to Part B Rebilling demonstration
- CMS's recent solicitation and summary of stakeholder comments on this problem published in the CY 2013 Outpatient Prospective Payment System Final Rule
- A discussion of recent litigation filed by the American Hospital Association challenging CMS policy and a class action lawsuit brought by Medicare beneficiaries
- Potential solutions and whether they require sub-regulatory, regulatory or legislative changes

Speakers:

William E. Hopkins, Brown McCarroll, LLP, Austin, TX

Mark Polston, Healthcare, King & Spalding, Washington, DC

3:45-5:00

Once More unto the Breach! Security Rule Compliance, Risk Assessments, Risk Mitigation Strategies, and What to Do When Things Go Wrong

Sponsored by: eHealth, Privacy & Security Interest Group

It is clear that OCR enforcement of the Security Standards has become a reality, and equally clear that provider compliance with the Security Standards is not yet comprehensive and universal. This session will discuss recent OCR enforcement trends, provider compliance efforts, and an evaluation of alternative risk mitigation strategies, such as cyberliability insurance. And if all else fails, we will also evaluate how non-compliance with the Security Standards transitions into breach notification duties.

Moderator:

Joel Wakefield, CopperSmith, Schermer & Brockelman, Phoenix, AZ

Speakers:

Elizabeth Callahan-Morris, Hall Render, Troy, MI

Leon Rodriguez, Director, Office for Civil Rights, Department of Health & Human Services, Washington, DC

SATURDAY, 2/23/13

8:00-11:30

Section Council Meeting

Open to all attendees

12:15-5:30

14th Annual Margarita Cup Golf Outing

Crandon Golf Key Biscayne

Ticket Event - \$250 includes 18 holes, lunch, and shuttle to and from site

Crandon Golf Key Biscayne is a championship 18-hole golf course located on the "island paradise" of Key Biscayne. It is the perfect alternative to civilization where you can spend a day enveloped by the tropics. Come out for an exciting event and network with your fellow colleagues.

12:15-5:30

Taste of South Beach Culinary Tour and Scenic Boat Tour

Ticket Event - \$150

Experience a Fun and Engaging Architectural, Historical & Culinary Walking Tour - With a Pronounced Cultural Aspect. From five-star gourmet to hole-in-the-wall delicious, if you really want to get a taste of Miami's melting-pot with its predominate Latin and European influences, join us as we'll uncover the hotspots for Ceviche, authentic Empanadas, true French Lobster Bisque, the classic Cuban sandwich, Pisco Sour and so much more with our own personal guide.

This tour is a "melting pot of cultures" and we'll be sitting down at half of the restaurants we visit – and savor different bites and wine standing and on the go. At the South Beach Food Tour, we will show you the hidden treasures inside the beating heart of the beach.

Additionally, we will take a boat from the hotel on a one hour scenic coastal tour before being dropped off on south beach for our culinary tour. Snacks and wine are included.

6:00-9:00

Chair's Reception and Margarita Cup Awards Ceremony

Enjoy cocktails and hors d'oeuvres during this final celebration hosted by the ABA Health Law Section Chair, David Douglass. We will recap the highlights of the conference and award the Margarita Cup trophy to this year's winning golf team.

CONFERENCE INFORMATION

REGISTRATION:

Register by **January 30, 2013** for early bird registration fees and by **February 3, 2013** to be included in the advance registration list. Registration will be accepted only when accompanied by payment.

Online <http://ambar.org/EMI2013>
Fax: (312) 988-5528
U.S. Mail: American Bar Association
Health Law Section
321 N. Clark St., MS 18.1
Chicago, IL 60654

ONSITE REGISTRATION:

Please call (312) 988-5146 by **FEBRUARY 15, 2013** to ensure space availability. Onsite registration fees will only be accepted when accompanied by check, money order, American Express, MasterCard, or Visa.

CANCELLATION POLICY:

Tuition, less a \$50 handling charge for each registration, will be refunded upon written cancellation received no later than **FEBRUARY 4, 2013**. Cancellations received after this date cannot be refunded but substitutions are encouraged. The ABA reserves the right to cancel any program and assumes no responsibility for personal expenses.

REGISTRATION FEE:

Your payment will cover admission to the program, continental breakfasts, coffee breaks, ticket to an Interest Group Lunch each day, receptions, and an online version of the course materials.

INTEREST GROUP LUNCHES:

Registrants are encouraged to attend the Interest Group lunch of their choice on both Thursday and Friday. There is no additional charge for these lunches but registrants must reserve a spot.

HOTEL INFORMATION:

The conference will be held at the Miami Marriott Biscayne Bay located at 1633 North Bayshore Drive, Miami, FL 33132. Call (305) 374-3900 no later than **JANUARY 14, 2013**. Please mention the ABA Health Law 14th Annual Emerging Issues in Healthcare Law Conference to receive the special rate of \$229 for a single or double. A limited number of government rate rooms have been reserved on a first available basis at the rate of \$169 for a single or double.

AIRLINE INFORMATION:

The Miami Marriott Biscayne Bay is located 7 miles from the Miami International Airport (MIA). Discounted fares are available from ABA Orbitz for Business including negotiated discounts on American, United and Virgin America Airlines. To book online, go to www.americanbar.org/travel > click on the Orbitz for Business logo at the top of the page > read the instructions under the Travel Paid by Self box. For assistance with online or offline reservations using the ABA Orbitz for Business website, call toll free 877-222-4185.

Discounts can also be obtained directly from the carrier. For American Airlines call 800-433-1790 and use the code **A1911SS**. For United Airlines call 800-521-4041 and use the code **578IG**.

CLE CREDIT:

CLE credit has been requested from most states with general mandatory continuing education requirements for lawyers. For information on the approved number of credit hours to be awarded by each state, please contact the Health Law Section directly at (312) 988-5532 after February 1, 2013.

HEALTH LAW SECTION MEMBERSHIP:

As an added bonus, the member's tuition rate will be available to registrants who become members of the ABA Health Law Section through the registration form. Membership dues are not deductible as charitable contributions for federal income tax purposes, but such dues may be deductible as a business expense.

TAX DEDUCTION FOR EDUCATIONAL EXPENSES:

An income tax deduction may be allowed for educational expenses undertaken to maintain or improve professional skills. This includes registration fees, travel, meals, and lodging expenses. (see Treas. Reg. 1.162-5) (Coughlin vs. Commissioners, 203 F 2d 307)

SERVICES FOR PERSONS WITH DISABILITIES:

If special arrangements are required for an individual with a disability to attend this program, please contact the ABA Health Law Section at (312) 988-5146.

DRESS CODE:

Business casual attire is appropriate for all meetings, CLE programs and social events during the program. However, the meeting rooms tend to be cool so be sure to carry a sweater or light jacket.

TUITION ASSISTANCE:

A limited number of registration fee reductions are available for government employees, academics, law students, and public interest lawyers employed with nonprofit organizations. No full tuition waivers are available. The fee-reductions will be determined on a one-time only, case-by-case, first-come first-serve basis. To apply, send a letter outlining the basis for your request of a fee reduction to Amy Alder, Senior Meeting Planner, ABA Health Law Section, 321 N. Clark St., Chicago, IL 60654. Deadline for receipt: January 28, 2013. No cases will be considered after the deadline, and all standard registration fee rates will apply after January 28, 2013.

REGISTRATION

AMERICAN BAR ASSOCIATION HEALTH LAW SECTION
14TH ANNUAL CONFERENCE ON EMERGING ISSUES IN HEALTHCARE LAW

Follow us on Twitter for additional EMI news and updates #EMI2013

2 WAYS TO REGISTER

ONLINE
www.ambar.org/EMI2013

BY MAIL
ABA Health Law Section
321 N. Clark St., MS 18.1
Chicago, IL 60654

Name

First Name for Name Badge

Company/Firm Name

Address

City, State, Zip

Phone

E-Mail Address

☐ Yes, I am bringing a spouse/guest (name)

ABA ID #

State(s) in which you are licensed (please list all)

☐ Please email me regarding hotel room share

☐ I am a first time attendee

Part A

REGISTRATION FEES

Registration fees are all inclusive and include all 3 days of educational programming, CLE, 2 luncheons, 3 receptions and an electronic written course materials.

	On or before 1/30/13	After 1/30/13
General Attendees:	\$1195	\$1295
ABA Member:	\$995	\$1095
ABA Health Law Member/ Sponsoring Section Member Rate:	\$895	\$995
Government/Academic: <i>Must be Full time</i>	\$325	\$425
Student:	\$100	\$150

Part B

INTEREST GROUP LUNCHESES

Interest Group Lunches are included in your registration fee. Please indicate your attendance to guarantee a boxed lunch.

Thursday Interest Group Lunch

☐ Yes, I will attend

Friday Interest Group Lunch

☐ Yes, I will attend

Please share any dietary restrictions:

☐ Kosher ☐ Lactose Intolerant ☐ Vegetarian

☐ Food Allergy: _____

Part C

POST CONFERENCE RECREATION

☐ \$150 Private Boat Tour/Taste of South Beach

☐ \$250 14th Annual Margarita Cup Golf Tournament

Part D

HEALTH LAW SECTION MEMBERSHIP

☐ Yes, please enroll me in the Section of Health Law. I am a member of the ABA. I understand that by joining, I am entitled to the Section Member Registration fee, a \$100 savings!

Dues: \$50. ID # _____

TOTAL FEES

Part A – Registration Fee \$

Part C – Post-Conference Recreation \$

Part D – Section Membership \$

AMOUNT DUE \$

METHOD OF PAYMENT

☐ Check enclosed (payable to American Bar Association)

☐ American Express ☐ MasterCard ☐ VISA

Card #

Exp. Date

Cardholder

Signature

AMERICAN BAR ASSOCIATION HEALTH LAW SECTION

14TH ANNUAL CONFERENCE ON
**EMERGING ISSUES
IN
HEALTHCARE LAW**

FEBRUARY 20-23, 2013

MIAMI MARRIOTT BISCAYNE BAY, MIAMI, FL

FUTURE EVENTS

June 2013

Physician Legal Issues Conference
Radisson Blu Aqua Hotel
Chicago, IL

December 9-10, 2013

Washington Health Law Summit
The Ritz Carlton
Washington, DC

February 26-March 1, 2014

Emerging Issues in Healthcare Law
Wigwam Resort
Litchfield Park, AZ

Stay up-to-date with all things EMI!

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ABA Health Law Section (MS 18.1)
321 N. Clark St.
Chicago, IL 60654



Register by Smart Phone