



Legal and Compliance Issues in Biomedical
Innovation **January 26, 2011**

Legal Issues Affecting Academic Medical Centers and
Other Teaching Institutions **January 27-28, 2011**

Ritz-Carlton Hotel • Washington, DC

Huron
CONSULTING GROUP

Huron Consulting Group has provided sponsorship in support of the Academic Medical Centers program.

Legal and Compliance Issues in Biomedical Innovation—January 26, 2011

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions—January 27-28, 2011

The American Health Lawyers Association is pleased to present the Legal and Compliance Issues in Biomedical Innovation and Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions programs. The one-day Biomedical Innovation program is strategically placed the day before the Legal Issues for Academic Medical Centers and Other Teaching Institutions. This combination will bring together the brightest legal minds representing pharmaceutical, biotech, and medical device companies with their academic medical center counterparts, all focused on the issues that define their interaction. The content, exchange, and networking will be unique and beneficial to counsel and compliance officers for all of these institutions.

Program Materials All materials will be available on a website prior to the programs and handed out on CD at the program. For those who still do want the binder(s), they will be available for an additional fee; please order on the registration form.

Continuing Education Participants will be given continuing education forms for each program. Forms must be completed and returned to AHLA staff to receive credits in most states. The Biomedical Innovation seminar is worth approximately 7.25 continuing education credits based on a 60-minute hour, 8.7 credits based on a 50-minute hour, and 8.0 CPE credits. The Academic Medical Centers program is worth approximately 12.0 (including 1.0 ethics) continuing education credits based on a 60-minute hour,

14.4 (including 1.2 ethics) credits based on a 50-minute hour, and 14.0 CPE credits.

AHLA is registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National Registry of CPE Sponsors. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be addressed to the National Registry of CPE Sponsors, 150 Fourth Avenue North, Suite 700, Nashville, TN 37219-2417. NASBA's web site is located at <http://www.nasba.org/>.

These programs are designed to be an update on developments in the area of life sciences and academic medical centers. There are no prerequisites or advanced preparations required to register for this group live program. Those seeking accounting credits should be familiar with the basic concepts of law and terminology associated with this area in order to obtain the full educational benefit of both programs.

Exhibitors/Sponsors AHLA would like to thank the following companies for their support and encourages attendees to visit their exhibit booths:

- ◆ **HORNE LLP**
- ◆ **Huron Consulting Group** (exhibitor and sponsor of the Academic Medical Centers program)
- ◆ **Pershing Yoakley & Associates** (exhibitor and sponsor of the Teaching Hospitals and Academic Medical Centers Practice Group Luncheon)

Hotel Reservations

Ritz-Carlton Hotel
1150 22nd Street, NW
Washington, DC 20037
Reservations: (202) 835-0500

Hotel accommodations are not included in the registration fee. AHLA has reserved a block of rooms at the Ritz-Carlton Hotel at a discounted rate of \$255 per night. To make reservations, please call (202) 835-0500. The room block expires Wednesday, January 5, 2011. Please make your reservations early. The room block may sell out prior to the hotel cutoff.

Special Needs If you have needs requiring special assistance or accommodations, including special dietary needs, or have questions about accessibility issues at the program, contact our special needs coordinator, Valerie Eshleman at (202) 833-0784 or veshleman@healthlawyers.org.

Biomedical Innovation Planning Committee:

Holly Thames Lutz, Esq., Program Co-Chair
Maureen Bennett, Esq., Program Co-Chair
Melinda Golub, Esq.
Marc B. Wilenzick, Esq.

Academic Medical Centers Planning Committee:

Ann T. Hollenbeck, Esq., Program Co-Chair
Jeff M. Sconyers, Esq., Program Co-Chair
Ann N. James, Esq.
Karen Fisher, JD
Holley Thames Lutz, Esq.

Biomedical Innovation Agenda

Wednesday, January 26, 2011

7:00 am-5:30 pm

Registration and Information

GENERAL SESSION

8:00-8:15 am

Welcome and Introduction

Gerald M. Griffith, AHLA President-Elect

Maureen Bennett, Program Co-Chair

Holly Thames Lutz, Program Co-Chair

8:15-8:45 am

Disruptive Innovation:

Medical Trends to Watch in 2011

Margaret A. Anderson

8:45-9:45 am

Compliance, Enforcement and Prosecution Issues

Paul Kaufman

Michael K. Loucks

Howard Sklamberg

9:45-11:00 am

Conflicts of Interest

Mark Wilenzick (Moderator)

Guy M. Chisolm III

Tanaz Dutia

Sally J. Rockey

Thomas P. Stossel

CONCURRENT SESSIONS

11:15 am-12:30 pm Extended Sessions

A. Comparative Effectiveness:

What It Is and Why it Matters to You

(not repeated)

Leah Hole-Curry

Demetrios Kouzoukas

- ◆ What is comparative effectiveness and why does it matter to life science and health care lawyers?
- ◆ The historical relationship between cost and coverage for Medicare and other payors
- ◆ Developments in litigation over least costly alternative policies
- ◆ The roles of PCORI, AHRQ, and NIH

B. Global Health- International Clinical Trials Agreements

Maureen Bennett (Moderator)

Jan Murray

William Nicholson

Jason Staples

12:30-1:45 pm

Lunch on your own or attend the

Life Sciences Practice Group Luncheon

(limited attendance; additional fee;

pre-registration required); See pages 20-21

The New Approval Pathway for Biosimilars: Next Steps, Open Issues and Implications for the Biotech and Generic Drug Industries

Madison C. Jellins, Esq.

Alston & Bird LLP, Menlo Park, CA

CONCURRENT SESSIONS

1:55-2:55 pm

C. Wrestling over Human Tissue: Yours, Mine or Ours?

Doreen D. Kornrumpf

Stacey Meadows

- ◆ Developing policies on use of tissue for research purposes – who participates; what facilities are covered; what is the scope of the policy, e.g. collection, storage, distribution, use, donor privacy and confidentiality, and material transfer agreements
- ◆ Considering commercial use of tissue to address biotechnology companies' requests, versus adopting a no commercial use or sale of tissue policy
- ◆ Clarifying the respective roles of hospital staff, researchers, the IRB, and Research Administration, with particular focus on where roles intersect, e.g. securing consent, promoting the academic medical center mission, facilitating participation in clinical trials

Biomedical Innovation Agenda

- ◆ Securing adequate patient consent for removal and distribution of tissue—is there a need for a specific tissue consent form in addition to the routine procedural consent?
- ◆ Managing patient expectations through clear and broadly understood physician/researcher/patient communications
- ◆ Handling media attention on this issue

D. MSP Mandatory Reporting – Implications in the Clinical Trial Context

Rachel Nosowsky
Janice Ziegler

- ◆ An overview of the MSP laws, including a summary of the mandatory reporting requirements (and potential penalties for non-compliance);
- ◆ A history of the issues surrounding potential application of the MSP laws to clinical trials and a summary of the recent CMS Alert;
- ◆ Practical implications, including relationship with health privacy laws; options for negotiating clinical trial agreements; and special considerations in investigator-initiated trials

3:05-4:20 pm Extended Sessions

E. Stem Cell Research

(not repeated)

R. Alta Charo

Samuel B. Casey

Robert P. Charrow

B. Global Health- International Clinical Trials Agreements (repeat)

4:30-5:30 pm

C. Wrestling over Human Tissue: Yours, Mine or Ours?

(repeat)

D. MSP Mandatory Reporting – Implications in the Clinical Trial Context

(repeat)

Adjournment

Legal and Compliance Issues in Biomedical Innovation At-A-Glance

Wednesday, January 26, 2011

7:00 am– 5:30 pm	Registration and Information	
8:00– 11:00 am	<p>GENERAL SESSION 8:00–8:15 am Welcome and Introduction <i>Griffith, Bennett, Lutz</i></p> <p>8:15–8:45 am Disruptive Innovation: Medical Trends to Watch in 2011 <i>Anderson</i></p> <p>8:45–9:45 am Compliance, Enforcement and Prosecution Issues <i>Kaufman, Loucks, Sklamberg</i></p> <p>9:45–11:00 am Conflicts of Interest <i>Wilenzick (Moderator), Chisolm, Dutia, Rockey, Stossel</i></p>	
11:00– 11:15 am	Break	
11:15 am– 12:30 pm Extended Sessions	<p>A. Comparative Effectiveness: What It Is and Why It Matters to You (not repeated)</p> <p><i>Hole-Curry</i> <i>Kouzoukas</i></p>	<p>B. Global Health – International Clinical Trials Agreements</p> <p><i>Bennett (Moderator)</i> <i>Murray</i> <i>Nicholson</i> <i>Staples</i></p>
12:30– 1:45 pm	<p>Lunch on your own or attend the Life Sciences Practice Group Luncheon (limited attendance; additional fee; pre-registration required; see pages 20-21)</p> <p>The New Approval Pathway for Biosimilars: Next Steps, Open Issues and Implications for the Biotech and Generic Drug Industries</p>	

Legal and Compliance Issues in Biomedical Innovation At-A-Glance

Wednesday, January 26, 2011 (continued)

1:55– 2:55 pm	<p>C. Wrestling over Human Tissue: Yours, Mine or Ours?</p> <p><i>Kornrumpf</i> <i>Meadows</i></p>	<p>D. MSP Mandatory Reporting – Implications in the Clinical Trial Context</p> <p><i>Nosowsky</i> <i>Ziegler</i></p>
3:05– 4:20 pm Extended Sessions	<p>E. Stem Cell Research (not repeated)</p> <p><i>Charo</i> <i>Casey</i> <i>Charrow</i></p>	<p>B. Global Health – International Clinical Trials Agreements (repeat)</p> <p><i>Bennett (Moderator)</i> <i>Murray</i> <i>Nicholson</i> <i>Staples</i></p>
4:30– 5:30 pm	<p>C. Wrestling over Human Tissue: Yours, Mine or Ours? (repeat)</p> <p><i>Kornrumpf</i> <i>Meadows</i></p>	<p>D. MSP Mandatory Reporting – Implications in the Clinical Trial Context (repeat)</p> <p><i>Nosowsky</i> <i>Ziegler</i></p>

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Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions Agenda

Thursday, January 27, 2011

7:00 am–6:00 pm

Registration and Information

GENERAL SESSION

8:00–8:15 am

Welcome and Introduction

Gerald M. Griffith, AHLA President-Elect

Ann T. Hollenbeck, Program Co-Chair

Jeff M. Sconyers, Program Co-Chair

8:15–9:00 am

Keynote Address: Healthcare Reform – A Tipping Point for Academic Medical Centers

Darrell G. Kirch

9:00–9:30 am

Keynote Address: Reform and the New Congress – What Does It Mean for Academic Medical Centers?

Atul Grover

9:30–10:15 am

Academic Medical Centers and Healthcare Reform: Meeting the Challenge

Nancy E. Forbes

Beth Schermer

Jeff M. Sconyers

- ◆ Challenges facing academic medical centers following passage of federal healthcare reform legislation, the 2010 mid-term elections, and other market forces at work
- ◆ Effect of PPACA on teaching, education, research, and safety net services
- ◆ AMCs and accountable care organizations
- ◆ Research funding relationships with an NIH under stress
- ◆ Privacy and research: In conflict?

10:15–10:45 am

Conflicts of Interest

Lewis Morris

10:45–11:00 am

Break sponsored by Huron Consulting Group

CONCURRENT SESSIONS

11:00 am–12:00 noon

A. Social Media in the Academic Medical Center: Physicians, Students, Patients, and Employees – Oh My!

Jenny Barnes

- ◆ Social media policy development: Learn how social media issues arose at OSU Medical Center, and why your mission, vision and values matter

- ◆ Medical staff blogging: They just can't resist. Real stories from the front-line, and guidelines to avoid HIPAA breaches
- ◆ Future web and reputation issues: Look at where the future web is headed. Lies are a problem, but what about misreputations!
- ◆ Practical legal advice: Look to the off-line world for guidance. Should entities use social media for pre-employment background checks? What recent federal law related to advertising do you need to know about?

B. Clinical Trials Update: Legal, Ethical and Operational Perspectives on MSP and Subject Injury, Clinical Trial Coding and Medicare Advantage Beneficiaries

Leah B. Guidry

Holley Thames Lutz

Melissa L. Markey

- ◆ Medicare Secondary Payer and its implications in the context of clinical trials
- ◆ The implications from legal, ethical and operational perspectives of recent guidance from CMS Office of Financial Management/ Financial Services Group
- ◆ Clinical Trial Coding Requirements – coding and modifier requirements for clinical trial claims (Diagnostic Code V70.7, Condition Code 30, Q0/Q1 modifiers), when each is

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions Agenda

applied to the clinical trial participant's claims and best practices of how to identify these claims in the revenue cycle

- ◆ Medicare Advantage beneficiaries' participation in clinical trials is not covered by their commercial providers

C. Up the Ladder or Under the Bus? Legal Ethics Issues When Management and Counsel Become Adversaries

William W. Horton

Jeff M. Sconyers

- ◆ Ethical obligations to a client that becomes adverse to the lawyer
- ◆ Privilege and confidentiality vs. self-defense: Parameters and pitfalls
- ◆ Interactions between general counsel and independent counsel when general counsel may be at risk
- ◆ Who really represents the organization when conflict arises?

12:00 noon–1:15 pm

Lunch on your own or attend the Teaching Hospitals and Academic Medical Centers Practice Group Luncheon, sponsored by Pershing Yoakley & Associates
(limited attendance; additional fee; pre-registration required – please see p. 20-21)

From Stem Cells to Jail Cells: The Tortured History of Embryo Research

R. Alta Charo

Warren P. Knowles Professor of Law and Bioethics, University of Wisconsin at Madison Madison, WI

GENERAL SESSION

1:30–2:30 pm

Patient Autonomy, Money and Clinical Research

Jennifer A. Stiller (Moderator)

Ellen W. Clayton

David Korn

- ◆ How can we encourage robust clinical research while at the same time taking into consideration patient autonomy?
- ◆ What role should protection of intellectual property rights have when the “property” in question is the fruits of clinical research?
- ◆ The Belmont Principles require respect for human autonomy and “fairness in distribution” of the research’s burdens and benefits. Are these objectives fundamentally incompatible?
- ◆ Should people whose tissue specimens are used for clinical research be able to require that the fruits of that research be made widely available, without excessive charges,

to the medical profession, patients, and other researchers?

CONCURRENT SESSIONS

2:45–3:45 pm

D. Taking the Lead in ACO Development: The Academic Medical Center’s Role in ACO Development

Susan F. Harris

Beth Schermer

- ◆ ACO organization, financial and delivery system strengths and weaknesses to initiate and lead in the development of accountable care organizations and shared savings payments
- ◆ The ingredients for accountable payment; the building blocks to receive risk or value based payment within a broader provider-driven organization while establishing a culture of care coordination
- ◆ The role of many academic medical centers as centers of excellence and safety net providers, and the potential synergy of these roles with ACO development within a broader community network
- ◆ Legal issues that affect the academic medical center’s engagement in accountable care organizations and payment, including anti-kickback, Stark, civil monetary penalty, antitrust and state insurance laws

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions Agenda

E. Clinical Research Enforcement Initiatives and False Claims Act Update Relevant to Academic Medical Centers

Gary W. Eiland

- ◆ Enhanced compliance and enforcement authority from FERA and healthcare reform legislation
- ◆ Recent agency and DOJ enforcement actions and *qui tam* litigation and settlements involving academic medical centers
- ◆ Clinical research compliance risks and agency and industry guidance
- ◆ Enforcement initiatives and settlements regarding allocation of costs to award accounts, cost transfers, effort reporting, indirect cost rates, and other issues
- ◆ Practical strategies for assessing internal compliance and minimizing False Claims Act risks

F. New Developments in Privacy and Research

Kristen B. Rosati

- ◆ The prohibition against the “sale” of health information
- ◆ Research authorizations
- ◆ Business associate agreements in research
- ◆ Other developments

4:00–5:15 pm Extended Sessions

G. Stark, Anti-Kickback, and False Claims Act Issues for Academic Medical Centers: How Healthcare Reform Will Shift the Playing Field

Lisa M. Ohrin

Robert A. Wade

- ◆ Recent statutory and regulatory changes to the Stark Law
- ◆ Recent case law and settlements involving the Anti-kickback Statute, Stark Law and False Claims Act
- ◆ The Stark Self-disclosure Protocol mandated by healthcare reform: How does it work and how is it working?
- ◆ The impact of fraud and abuse law on innovative service delivery models and relationships with physicians: Gainsharing, Accountable Care Organizations, medical homes: Can they exist within the framework of the Stark Law and Anti-kickback Statute?
- ◆ Fraud and abuse audit and reporting issues

H. Reimbursement and Operational Issues Associated with Residency Programs

Karen Fisher

Nancy C. LeGros

Andrew D. Ruskin

- ◆ Medicare reimbursement fundamentals, including for new teaching hospitals
- ◆ GME and IME provisions in the Affordable Care Act
- ◆ Issues raised by non-accredited residency programs
- ◆ Resident moonlighting
- ◆ Update on resident stipends and FICA

4:00–6:00 pm

J. Public Interest Convener Session: “Objectivity v. Commercialization” – AMC Institutional Conflicts of Interest in Research: An Academic Discussion

(not repeated)

Jeff M. Sconyers (Moderator)

Dawn R. Crumel

Harvey V. Fineberg

Stuart Horowitz

Ann N. James

Melissa L. Markey

Lewis Morris

Sally J. Rockey

In support of scientific research, society places value on two potentially inconsistent objectives: promoting objectivity in

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions Agenda

the scientific process while simultaneously promoting commercialization of the results of that process. These potentially inconsistent objectives at the institutional level will be explored in an interactive discussion between individuals representing academic medical centers and participants from research and government agencies. A summary of the academic collaborative discussion will be presented in a White Paper as a part of AHLA's Public Interest Committee's mission to serve as a public resource on selected legal healthcare issues.

- 12 5:15–6:30 pm
Reception sponsored by Huron Consulting Group
(attendees, speakers, and registered spouses and guests welcome)

Friday, January 28, 2011

7:00 am–3:20 pm
Registration and Information

- 7:00–8:00 am
Continental Breakfast sponsored by Huron Consulting Group
(attendees, speakers and registered spouses and guests welcome)

CONCURRENT SESSIONS

8:00–9:15 am Extended Sessions

K. Current Issues in Conflicts of Interest in Research (not repeated)

Marleina T. Davis

Ann N. James

Michael B. Lampert

Heather H. Pierce

- ◆ Recent legal developments, e.g.—
 - PPACA (e.g., sunshine provisions)
 - May 2010 Notice of Proposed Rulemaking, including comments and any final rule adopted prior to the conference
 - Government enforcement
- ◆ Policy implications of legal developments, and new directions in policy
- ◆ Day-to-day operations and consequences of recent developments, e.g.—
 - Institutional policies
 - Faculty disclosure
 - Institutional assessment of faculty conflicts
 - Conflict management plans
 - Mitigation plans
 - Institutional conflicts

G. Stark, Anti-Kickback and False Claims Act Issues for AMCs: How Healthcare Reform Will Shift the Playing Field (repeat)

H. Reimbursement and Operational Issues Associated with Residency Programs (repeat)

9:30-10:30 am

- #### L. Impact of Healthcare Reform on Tax-Exempt Requirements for AMCs/Teaching Hospitals (not repeated)
- Ann T. Hollenbeck*
Sean Scally

M. Audacious Goals and Grand Plans: How a \$200 Million Ambulatory Care Center Joint Venture Obtained an OIG Advisory Opinion

Jesse A. Berg
Jennifer R. Bishop

- ◆ Process for seeking Advisory Opinions, including the regulatory issues which OIG is permitted to address, timing for requesting opinions and type and nature of communications with OIG personnel
- ◆ Framing initial request to, and subsequent communications, with the OIG, including the importance of telling the story of your organizations and their unique complexities to aid the OIG reviewers in their work
- ◆ Key regulatory issues and strategies for addressing those issues in the most positive light

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions Agenda

- ◆ Case study of the ambulatory care center joint venture approved by OIG in Advisory Opinion 10-15

- B. Clinical Trials Update: Legal, Ethical and Operational Perspectives on MSP and Subject Injury, Clinical Trial Coding, and Medicare Advantage Beneficiaries**
(repeat)

10:45–11:45 am

- N. Enterprise Risk Management: The New Necessity for Academic Medical Centers**
(not repeated)

Douglas Brown

Jeffrey D. Kahn

- ◆ Enterprise Risk Management (ERM): What is it and how can it be applied in academic medical center settings?
- ◆ Relationship of ERM and other institutional risk functions (audit, compliance, etc.)
- ◆ Governance implications of ERM
- ◆ Practical tips and tools for ERM implementation, including avoiding traps for the unwary

- D. Taking the Lead in ACO Development: The Academic Medical Centers Role in ACO Development** (repeat)

- E. Clinical Research Enforcement Initiatives and False Claims Act Update Relevant to Academic Medical Centers** (repeat)

11:50 am–1:00 pm

Lunch on your own

CONCURRENT SESSIONS

1:00–2:00 pm

- C. Up the Ladder or Under the Bus? Legal Ethics Issues When Management and Counsel Become Adversaries** (repeat)

- F. New Developments in Privacy and Research** (repeat)

2:10–3:10 pm

- A. Social Media in the Academic Medical Center: Physicians, Students, Patients, and Employees – Oh My!** (repeat)

- M. Audacious Goals and Grand Plans: How a \$200 Million Ambulatory Care Center Joint Venture Obtained an OIG Advisory Opinion** (repeat)

Adjournment

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions Faculty

PLANNING COMMITTEE

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Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions At-A-Glance

Thursday, January 27, 2011

7:00 am– 6:00 pm	Registration and Information		
8:00– 10:45 am	<p>GENERAL SESSION</p> <p>8:00–8:15 am Welcome and Introduction <i>Griffith, Hollenbeck, Sconyers</i></p> <p>8:15–9:00 am Keynote Address: Healthcare Reform – A Tipping Point for Academic Medical Centers <i>Kirch</i></p> <p>9:00–9:30 am Keynote Address: Reform and the New Congress – What Does It Mean for Academic Medical Centers? <i>Grover</i></p> <p>9:30–10:15 am Academic Medical Centers and Healthcare Reform: Meeting the Challenge <i>Forbes, Schermer, Sconyers</i></p> <p>10:15–10:45 am Conflicts of Interest <i>Morris</i></p>		
10:45– 11:00 am	Break sponsored by Huron Consulting Group		
11:00 am– 12:00 noon	<p>A. Social Media in the Academic Medical Center: Physicians, Students, Patients, and Employees – Oh My!</p> <p style="text-align: center;"><i>Barnes</i></p>	<p>B. Clinical Trials Update: Legal, Ethical and Operational Perspectives on MSP and Subject Injury, Clinical Trial Coding, and Medicare Advantage Beneficiaries</p> <p style="text-align: center;"><i>Guidry Lutz Markey</i></p>	<p>C. Up the Ladder or Under the Bus? Legal Ethics Issues When Management and Counsel Become Adversaries</p> <p style="text-align: center;"><i>Horton Sconyers</i></p>

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions At-A-Glance

Thursday, January 27, 2011 (continued)

12:00 noon– 1:15 pm	<p align="center">Lunch on your own or attend the Teaching Hospitals and Academic Medical Centers Practice Group Luncheon <i>sponsored by Pershing Yoakley & Associates</i> (limited attendance; additional fee; pre-registration required – see pages 20-21)</p>			
1:30– 2:30 pm	<p align="center">GENERAL SESSION Patient Autonomy, Money, and Clinical Research <i>Stiller, Clayton, Korn</i></p>			
2:45– 3:45 pm	<p align="center">D. Taking the Lead in ACO Development: The Academic Medical Center's Role in ACO Development</p> <p align="center"><i>Harris Schermer</i></p>	<p align="center">E. Clinical Research Enforcement Initiatives and False Claims Act Update Relevant to Academic Medical Centers</p> <p align="center"><i>Eiland</i></p>	<p align="center">F. New Developments in Privacy and Research</p> <p align="center"><i>Rosati</i></p>	
4:00– 5:15 pm Extended Sessions	<p>G. Stark, Anti-Kickback, and False Claims Act Issues for Academic Medical Centers: How Healthcare Reform Will Shift the Playing Field</p> <p align="center"><i>Ohrin Wade</i></p>	<p>H. Reimbursement and Operational Issues Associated with Residency Programs</p> <p align="center"><i>Fisher Ruskin LeGros</i></p>	4:00– 6:00 pm	<p>J. Public Interest Convener Session: “Objectivity v. Commercialization” – AMC Institutional Conflicts of Interest in Research: An Academic Discussion (not repeated)</p> <p align="center"><i>Sconyers – (Moderator) Crumel Fineberg Horowitz James Markey Morris Rockey</i></p>
5:15– 6:30 pm	<p align="center">Reception sponsored by Huron Consulting Group (attendees, speakers, and registered spouses and guests welcome)</p>			

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions At-A-Glance

Friday, January 28, 2011

7:00 am– 3:20 pm	Registration and Information		
7:00– 8:00 am	Continental Breakfast <i>sponsored by Huron Consulting Group</i> (attendees, speakers and registered spouses and guests welcome)		
8:00– 9:15 am Extended Sessions	K. Current Issues in Conflicts of Interest in Research (not repeated) <i>Davis James Lampert Pierce</i>	G. Stark, Anti-Kickback and False Claims Act Issues for AMCs: How Healthcare Reform Will Shift the Playing Field (repeat) <i>Ohrin Wade</i>	H. Reimbursement and Operational Issues Associated with Residency Programs (repeat) <i>Fisher Ruskin LeGros</i>
9:30– 10:30 am	L. Impact of Healthcare Reform on Tax-Exempt Requirements of AMCs/Teaching Hospitals (not repeated) <i>Hollenbeck Scally</i>	M. Audacious Goals and Grand Plans: How a \$200 Million Ambulatory Care Center Joint Venture Obtained an OIG Advisory Opinion <i>Berg Bishop</i>	B. Clinical Trials Update: Legal, Ethical and Operational Perspectives on MSP and Subject Injury, Clinical Trial Coding, and Medicare Advantage Beneficiaries (repeat) <i>Guidry Lutz Markey</i>

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions At-A-Glance

Friday, January 28, 2011 (continued)

10:45– 11:45 am	<p>N. Enterprise Risk Management: The New Necessity for Academic Medical Centers (not repeated)</p> <p><i>Brown Kahn</i></p>	<p>D. Taking the Lead in ACO Development: The AMC's Role in ACO Development (repeat)</p> <p><i>Harris Schermer</i></p>	<p>E. Clinical Research Enforcement Initiatives and False Claims Act Update Relevant to Academic Medical Centers (repeat)</p> <p><i>Eiland</i></p>
11:50 am– 1:00 pm	<p>Lunch on your own</p>		
1:00– 2:00 pm	<p>C. Up the Ladder or Under the Bus? Legal Ethics Issues When Management and Counsel Become Adversaries (repeat)</p> <p><i>Horton Sconyers</i></p>	<p>F. New Developments in Privacy and Research (repeat)</p> <p><i>Rosati</i></p>	
2:10– 3:10 pm	<p>A. Social Media in the Academic Medical Center: Physicians, Students, Patients, and Employees – Oh My! (repeat)</p> <p><i>Barnes</i></p>	<p>M. Audacious Goals and Grand Plans: How a \$200 Million Ambulatory Care Center Joint Venture Obtained an OIG Advisory Opinion (repeat)</p> <p><i>Berg Bishop</i></p>	

Biomedical Innovation/Academic Medical Centers Registration Form

To register: Remit payment and completed registration form by mail to the American Health Lawyers Association • P.O. Box 79340 • Baltimore, MD 21279-0340 or fax with credit card information to (202) 775-2482. To register by phone call (202) 833-0766. If any program is over-subscribed, only Health Lawyers members will be placed on a waiting list. On-site registrations will be accepted on a space-available basis only. **Click here to register online at www.healthlawyers.org/programs**

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Members: \$695 **Non-Members:** \$920

\$620 Each additional AHLA Member registering from same organization at same time on the same check or credit card.

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(Continued on page 21)

Biomedical Innovations/Academic Medical Centers Registration Form

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\$ _____ Biomedical Innovation Printed Course Materials (\$35)

\$ _____ Academic Medical Centers Program Only Registration Fee

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\$ _____ Academic Medical Centers Printed Course Materials (\$45)

\$ _____ Both Biomedical Innovation and Academic Medical
Centers Programs

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