

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions

January 21–22, 2010 Ritz-Carlton Hotel Washington, DC



*Huron Consulting Group
has provided sponsorship
in support of this program.*

Planning Committee:

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

Program Agenda

Thursday, January 21, 2010

7:00 am-5:15 pm

Registration and Information

GENERAL SESSION

8:00-8:15 am

Welcome and Introduction

Elizabeth Carder-Thompson,

AHLA President

Ann T. Hollenbeck, Program

Co-Chair

Jeffrey M. Sconyers, Program

Co-Chair

8:15-9:00 am

Keynote Address

David Dorsey

9:00-9:45 am

Keynote Address

Daniel R. Levinson

9:45-10:45 am

**Healthcare Reform: Implications
for Academic Medical Centers**

Nancy E. Forbes

Andrea M. Kahn-Kothmann

Beth Schermer

Susan Stayn

10:45-11:00 am

Break

CONCURRENT SESSIONS

11:00 am-12:00 noon

A. What's Old is New Again...

**Medicare Reimbursement/
Enforcement Initiatives that**

**TH/AMCs Should Keep on the
Radar**

Thomas E. Dowdell

Holley Thames Lutz

- Supervision for outpatient services (therapeutic/diagnostic)
- DRG payment window...who knew we would be still talking about this?
- Provider-based status
- EMTALA changes
- Quality of care
- HAC/POA issues

B. The September 2009 Pfizer Settlement and Issues Affecting Academic Medical Centers

Sara Bloom

Joshua S. Levy

- Pfizer settlement: Products at issue, nature of government allegations and components of settlement, key aspects of Corporate Integrity Agreement
- Trend toward publication of all payments on the internet
- Publication strategies and disclosure of role of drafter or sponsor
- Academics working as promotional speakers and consultants for industry
- Independent CME programs
- Sales representatives access to medical institutions

Program Agenda

C. Graduate Medical Education Reimbursement in a Changing Healthcare Payment Environment: Emerging New Issues and Persistent Old Ones

Karen S. Fisher

Andrew D. Ruskin

- Continued compliance pitfalls pertaining to site of training and type of training activity
- GME and IME provisions in healthcare reform legislation
- CMS' position on new medical residency training programs
- Recent trends in GME/IME case law

12:00 noon-1:15 pm

Lunch on your own or attend the Teaching Hospitals and Academic Medical Centers Practice Group Luncheon sponsored by Sullivan, Cotter and Associates, Inc.

(limited attendance; additional fee; pre-registration required)

The Role of Academic Medical Centers in Healthcare Reform

Allyson Y. Schwartz

Member of Congress,

Washington, DC

CONCURRENT SESSIONS

1:30-2:30 pm

D. It's Not Child's Play: Special Considerations for Pediatric Medicine and Research

(not repeated)

Dawn R. Crumel

Stephanie A. Webster

Teresa A. Williams

- Clinical trial issues in the pediatric setting, including IRB issues

- Consent issues, including protecting the rights of children to participate voluntarily in medical research
- Resolving conflicts between providers and parent(s)/guardian(s) about children's treatment and/or the release of records
- Current issues relating to off-label use of drugs and devices in children, including both when you can legally do it and potential liability risk

E. Why Your Organization Should Consider an External Review of Its Compliance Program

Thomas S. Crane

Leon Goldman

- Specific questions to ask about how your compliance program is functioning
- What type of external reviewer to seek
- How deep do you want to probe throughout the organization?
- Strategies for obtaining organizational buy-in to implement the recommendations

F. The New Audit Landscape: MICs, MACs and RACs (Medicaid Integrity Contractors, Medicare Administrative Contractors and Recovery Audit Contractors)

Andrew B. Wachler

- The roles of the various contractors and the types of claims contractors will be focused on initially and in the future
- Emerging issues and efforts to effectuate changes in Medicare policy

Program Agenda

- Current legal issues, proactive compliance measures and successful appeal strategies for in-house and outside counsel representing academic medical centers and teaching institutions
- Practical experiences and organizational tips

2:45-3:45 pm

G. The Who, What, and How of Accounting for Professional Services in Clinical Research

Lori Oliver

Margaret M. Peyton

- The interplay of regulatory guidance from different sub-agencies of HHS: CMS, through the Clinical Trial Policy, provides guidance on what Medicare will pay for and NIH, through Guidance for Grants and Contracts, provides guidance on what NIH will pay for in clinical research
- Creating guidance for faculty on what methodology to use to account for professional services based on the type of study, the type of service and the type of personnel
- General cost accounting principles guide development of reimbursement rates for professional research-only services
- Education and training – ongoing challenges

H. Legal Ethics: What's Confidentiality Got to Do with It? Resolving Transparency, Accountability and Privilege with the Best Interests of the Client

Almeta E. Cooper

Jeffrey M. Sconyers

- Attorney-client privilege in the context of the current trend for healthcare clients to desire and/or to demand transparency
- How to maintain the attorney-client privilege in relationship to
 - Peer review privilege
 - Quality improvement privilege
 - The attorney work-product doctrine
- Counseling the client on the pitfalls of transparency

B. The September 2009 Pfizer Settlement and Issues Affecting Academic Medical Centers (repeat)

4:00-5:15 pm Extended Sessions

J. Distinction without a Difference? Quality Improvement vs. Research (not repeated)

Demetrios L. Kouzoukas

Rachel Nosowsky

Laura Odwazny

- What is QI and how is it regulated?
- The distinctions between quality improvement and human subjects research
- The guidance issued by the Office for Human Research Protections on the subject

Program Agenda

- What unique opportunities and legal challenges are presented by multi-institutional QI initiatives?
- K. The HITECH Act: New Developments in Privacy, Security and Dollars**
Jodi G. Daniel
Kristen B. Rosati
- Minimizing risk under the new federal breach reporting requirements
 - Renegotiating business associate agreements to address new requirements and reduce risk
 - Implementing the new privacy regulations, such as withholding information from health plans for self-pay services, accounting for treatment, payment and healthcare operations and other significant changes
 - Preparing for Medicare and Medicaid incentives for EHR adoption, including meeting the “meaningful use” standards
 - Understanding the role of the Regional Extension Centers and Designated State Entities in encouraging HIT and HIE
- L. Let the Sunshine In: Addressing Conflicts of Interest in the Academic Medical Center**
Susan H. Ehringhaus
Ann N. James
Sally J. Rockey
- The scope of policies in the future and how teaching institutions might address some of the troublesome issues such as what standards should govern, how such conflicts can be managed, educating the patient community about physician relationships with industry, meaningful disclosure to patients and non-faculty providers
 - The evolving standards for divestiture and management, and how best to disclose such conflicts, as well as the issue of ICOI for leadership in the University, school, and department
 - NIH has been involved in the process of updating existing regulations governing financial conflicts of interest in PHS-sponsored research. A senior NIH official will provide perspective on the proposed rulemaking, including comments from the public, key issues for NIH, and timetable for the final rule
- 5:15-6:15 pm
Reception sponsored by Huron Consulting Group
 (attendees, speakers, and registered spouses and guests welcome)
- Friday, January 22, 2010**
 7:00 am-3:25 pm
Registration and Information
- 7:00-8:00 am
Continental Breakfast sponsored by Huron Consulting Group
 (attendees, speakers and registered spouses and guests welcome)

Program Agenda

CONCURRENT SESSIONS

8:00-9:15 am Extended Sessions

**M. Addressing Disruptive Behavior
Claims in an Academic
Environment: The Challenges that
Academic Medical Centers Face
and the Practical Solutions to
those Challenges**

(not repeated)

Michael L. Goodman

Julia C. Morris

Rachel Nosowesky

- What is and is not disruptive behavior and identifying its roots
- Toward prevention: Education, intervention and mediation
- Managing disruptive physician allegations in an academic environment: Employment and medical staff approaches
- The physician's perspective and how to work constructively with physicians' counsel when disputes arise

**K. The HITECH Act: New
Developments in Privacy,
Security and Dollars**
(repeat)

**L. Let the Sunshine In: Addressing
Conflicts of Interest in the
Academic Medical Center**
(repeat)

9:30-10:30 am

N. The National Vaccine Plan:

**Lessons Learned from Response
to the 2009 Influenza A/H1N1 and
the Role of Vaccination Mandates**
(not repeated)

Raymond A. Strikas

- The development of the National Vaccine Plan, its current status and timeline for completion, including its implications for research and provider education as well as clinical care
- The current status of the H1N1 vaccination program, and any "lessons learned" that will inform future vaccine development and distribution efforts
- State approaches to mandating vaccination, particularly influenza vaccination for healthcare workers and how/whether those state efforts relate to federal approaches on vaccination – the New York law will be examined as an example

**O. Stark and Fraud and Abuse Issues
for Academic Medical Centers**

Lisa M. Ohrin

Robert A. Wade

- Recent changes and case law involving the Anti-Kickback Statute and Stark Law
- Accountable Care Organizations and similar structures: Limitations imposed by the fraud and abuse laws
- Fraud and abuse audit and reporting issues

Program Agenda

G. The Who, What, and How of Accounting for Professional Services in Clinical Research
(repeat)

10:45-11:45 am

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

(not repeated)

Gary W. Eiland

Madhu Purewal

- Clinical research compliance risks including CMS' National Coverage Determination, NCD implementation issues and CMS "clarifications"
- Enforcement actions and compliance challenges regarding effort reporting, allocation of costs to award accounts, cost transfers, indirect cost rates, off-label use and other issues
- The OIG's research-targeted enforcement priorities for FY 2010
- Fraud Enforcement and Recovery Act amendments to the False Claims Act, increased enforcement funding, subsequent judicial interpretations and other proposed amendments
- Practical implications for academic medical centers

F. The New Audit Landscape: MICs, MACs, and RACs
(repeat)

H. Legal Ethics: What's Confidentiality Got to Do with It? Resolving Transparency, Accountability and Privilege with the Best Interests of the Client
(repeat)

11:50 am-1:05 pm

Program Group Luncheon sponsored by Huron Consulting Group
(attendees and speakers welcome)

Social Media in Healthcare: The Promise and the Perils
Robin J. Strongin

CONCURRENT SESSIONS

1:15-2:15 pm

A. What's Old is New Again... Medicare Reimbursement/ Enforcement Initiatives that TH/AMCs Should Keep on the Radar
(repeat)

E. Why Your Organization Should Consider an External Review of Its Compliance Program
(repeat)

2:25-3:25 pm

C. Graduate Medical Education Reimbursement in a Changing Healthcare Payment Environment: Emerging New Issues and Persistent Old Ones (repeat)

O. Stark and Fraud and Abuse Issues for Academic Medical Centers
(repeat)

ADJOURNMENT

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Program at a Glance

Thursday, January 21, 2010

7:00 am–5:15 pm	Registration and Information		
8:00–10:30 am	<p>GENERAL SESSION 8:00–8:15 am Welcome and Introduction <i>Carder-Thompson, Hollenbeck, Sconyers</i></p> <p>8:15-9:00 am Keynote Address <i>Dorsey</i></p> <p>9:00-9:45 am Keynote Address <i>Levinson</i></p> <p>9:45-10:45 am Healthcare Reform: Implications for Academic Medical Center <i>Forbes, Kahn-Kothmann, Schermer, Stayn</i></p>		
10:45–11:00 am	Break		
11:00 am–12:00 noon	<p>A. Medicare Reimbursement/ Enforcement Initiatives that TH/AMCs Should Keep on the Radar</p> <p><i>Dowdell Lutz</i></p>	<p>B. The September 2009 Pfizer Settlement and Issues Affecting Academic Medical Centers</p> <p><i>Bloom Levy</i></p>	<p>C. Graduate Medical Education Reimbursement in a Changing Healthcare Payment Environment</p> <p><i>Fisher Ruskin</i></p>
12:00 noon–1:15 pm	<p>Lunch on your own or attend the Teaching Hospitals and Academic Medical Centers Practice Group Luncheon sponsored by Sullivan, Cotter and Associates, Inc. (limited attendance; additional fee; pre-registration required. See pg 15.)</p>		
1:30–2:30 pm	<p>D. Special Considerations for Pediatric Medicine and Research (not repeated)</p> <p><i>Crumel Webster Williams</i></p>	<p>E. Why Your Organization Should Consider an External Review of Its Compliance Program</p> <p><i>Crane Goldman</i></p>	<p>F. The New Audit Landscape: MICs, MACs and RACs</p> <p><i>Wachler</i></p>

Program at a Glance

Thursday, January 21, 2010 *(continued)*

2:45– 3:45 pm	G. The Who, What, and How of Accounting for Professional Services in Clinical Research <i>Oliver Peyton</i>	H. Legal Ethics: Resolving Transparency, Accountability and Privilege with the Best Interests of the Client <i>Cooper Sconyers</i>	B. The September 2009 Pfizer Settlement and Issues Affecting Academic Medical Centers (repeat) <i>Bloom Levy</i>
4:00– 5:15 pm Extended Sessions	J. Distinction without a Difference? Quality Improvement vs. Research (not repeated) <i>Kouzoukas Nosowsky Odwazny</i>	K. The HITECH Act: New Developments in Privacy, Security and Dollars <i>Daniel Rosati</i>	L. Addressing Conflicts of Interest in the Academic Medical Center <i>Ehringhaus James Rockey</i>
5:15– 6:15 pm	Reception sponsored by Huron Consulting Group (attendees, speakers, and registered spouses and guests welcome)		

Friday, January 22, 2010

7:00 am– 3:25 pm	Registration and Information		
7:00– 8:00 am	Continental Breakfast sponsored by Huron Consulting Group (attendees, speakers and registered spouses and guests welcome)		
8:00– 9:15 am Extended Sessions	M. Addressing Disruptive Behavior Claims in an Academic Environment (not repeated) <i>Goodman Morris Nosowsky</i>	K. The HITECH Act: New Developments in Privacy, Security and Dollars (repeat) <i>Daniel Rosati</i>	L. Addressing Conflicts of Interest in the Academic Medical Center (repeat) <i>Ehringhaus James Rockey</i>

Program at a Glance

Friday, January 22, 2010 *(continued)*

9:30–10:30 am	N. Lessons Learned from Response to the 2009 Influenza A/H1N1 and the Role of Vaccination Mandates (not repeated) <i>Strikas</i>	O. Stark and Fraud and Abuse Issues for Academic Medical Centers <i>Ohrin Wade</i>	G. The Who, What, and How of Accounting for Professional Services in Clinical Research (repeat) <i>Oliver Peyton</i>
10:45–11:45 am	P. Clinical Research Enforcement Initiatives and False Claims Act Update Relevant to Academic Medical Centers (not repeated) <i>Eiland Purewal</i>	F. The New Audit Landscape: MICs, MACs and RACs (repeat) <i>Wachler</i>	H. Legal Ethics: Resolving Transparency, Accountability and Privilege with the Best Interests of the Client (repeat) <i>Cooper Sconyers</i>
11:50 am–1:05 pm	Program Group Luncheon sponsored by Huron Consulting Group (attendees and speakers welcome)		
1:15–2:15 pm	A. Medicare Reimbursement/ Enforcement Initiatives that TH/AMCs Should Keep on the Radar (repeat) <i>Dowdell Lutz</i>	E. Why Your Organization Should Consider an External Review of Its Compliance Program (repeat) <i>Crane Goldman</i>	
2:25–3:25 pm	C. Graduate Medical Education Reimbursement in a Changing Healthcare Payment Environment (repeat) <i>Fisher Ruskin</i>	O. Stark and Fraud and Abuse Issues for Academic Medical Centers (repeat) <i>Ohrin Wade</i>	

Program Information

Dates: January 21-22, 2010
Place: Ritz-Carlton Hotel
 1150 22nd Street, NW
 Washington, DC 20037
Phone: (202) 835-0500

Registration Fees:
**Postmarked and paid by
 December 30, 2009**
 \$695 For the first AHLA Member
 \$620 For each additional Member
 \$920 Non-Members

**Postmarked and paid between
 December 31, 2009 and
 January 17, 2010***
 \$820 For the first AHLA Member
 \$750 For each additional Member
 \$1045 Non-Members

Printed Course Materials: \$45

* Registration fees increase \$125 after this date.

If you have indicated an incorrect amount due to errors in addition or not being eligible for a specific rate, AHLA will charge the correct amount to the credit card you have supplied.

Discounted Registration Fees: Government employees, in-house counsel, academicians, solo practitioners and students: please call (202) 833-1100 prompt #2 for special discounted registration fees.

Spouse/Guest Fee: For an additional \$30 spouses and adult guests can register to attend the reception on Thursday evening and the breakfasts on Thursday and Friday mornings. Please sign up on the registration form. *(Children are welcome to attend these events at no additional charge.)*

Continuing Education: Participants will be given continuing education forms at

the program. Forms must be completed and returned to AHLA staff to receive credit. AHLA is an approved sponsor of continuing legal education credits in most states. This seminar will be worth approximately 12.0 continuing education credits (including 1.0 ethics credit) based on a 60-minute hour and 14.4 credits (including 1.2 ethics credits) based on a 50-minute hour.

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. Website: www.nasba.org. This seminar will be worth approximately 14.0 CPE credits.

This program is designed to be an update on developments in the area of teaching hospitals 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 this program.

Hotel Reservations: Hotel accommodations are not included in the registration fee. Call the Ritz-Carlton Hotel at (202) 835-0500. Please indicate that you are attending the AHLA program. Rooms at the group rate of \$255 for single/double occupancy are limited

Program Information

and may sell out prior to the **December 30, 2009** cut-off.

Membership: Dues are \$185 for those admitted to the Bar/graduated from college within the last four years; \$300 for those admitted/ graduated more than four but less than eight years ago; and \$345 for those admitted/graduated eight or more years ago. Dues are \$155 (or \$75 for electronic benefits) for government employees, paralegals, and full-time academicians; and \$15 for full-time law school students to receive benefits electronically. Include the applicable membership fee with your registration form and take advantage of the program registration fee for members.

Cancellations/Substitutions: Cancellations must be received in writing no later than January 14, 2010. Refunds will not be issued for cancellations received after this date. Registration fees, less a \$125 administrative fee, will be refunded approximately 3-4 weeks following the program. If you wish to send a substitute or need more information regarding refund, complaint and program cancellation policies, please call the Member Service

Center at (202) 833-1100 prompt #5. Please note that registration fees are based on the AHLA membership status of the individual who actually attends the program.

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.

Travel: Association Travel Concepts (ATC) has negotiated discounts with United, American, Enterprise and Hertz Rental Car to bring you special airfares and car rental rates lower than those available to the public. Discounts of 5-15% apply to travel on January 18-25, 2010. Some restrictions may apply and a service fee may apply. ATC will also search for the lowest available fare on any airline.

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email: [reservations\[at\]atcmeetings.com](mailto:reservations[at]atcmeetings.com)
www.atcmeetings.com (*follow the Member Travel links*)

Program Materials

AHLA is going green for the 2010 Academic Medical Centers Program! We are trying to reduce the amount of paper we use at our programs. This is both an effort at responsible environmental conservation, and an effort to increase the timeliness of the resources provided to our attendees. We will not automatically be printing binders for everyone. All materials will be available on a website prior to the program so attendees can print what they need for the sessions they plan to attend and handed out on CD at the program. For those who still do want the binder, they will be available for an additional fee; please order on the registration form on page 15.

Academic Medical Centers Program 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) 833-1100, prompt #2. If any program is over-subscribed, only AHLA members will be placed on a waiting list. On-site registrations will be accepted on a space-available basis only.

Name: _____ Member ID #: _____

First Name for Badge (if different than above): _____

Title: _____

Organization: _____

Address: _____

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Telephone: (_____) _____ Fax: (_____) _____

E-Mail: _____

Spouse/Guest Name _____

Early Registration Fees (faxed/postmarked and paid on or before December 30, 2009):

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

\$620 each additional member registering from same organization at same time on the same check or credit card payment

Registration Fees (faxed/postmarked and paid between December 31 and January 17, 2010):

Members: \$820 **Non-Members:** \$1,045

\$750 each additional member registering from same organization at same time on the same check or credit card payment

I will require: audio visual mobility

other assistance _____ I have special dietary needs

PAYMENT INFORMATION Please fill in applicable amount: (Sorry! Registrations cannot be processed unless accompanied by payment.)

\$ _____ Registration Fee

\$ _____ Teaching Hospitals and Academic Medical Centers (\$35 for members of the TH/AMC PG; \$45 for PG non-members; Thursday, January 21, 2010)

\$ _____ Printed Course Materials (\$45)

\$ _____ Spouse/Guest Fee (\$30)

\$ _____ Membership Dues (Date admitted to the bar/graduated: /)

\$ _____ Total Enclosed

Check enclosed (Make checks payable to American Health Lawyers Association)

Bill my credit card:   

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Please Note: Should your credit card total be miscalculated, AHLA will charge your credit card for the correct amount. To receive a refund of the registration fee paid minus \$125, cancellation notice must be received in writing by January 14, 2010. Please see page 14 of this brochure for AHLA's full refund policy.

Fed ID No. 23-7333380

Printed Course Materials

All attendees will receive an electronic version of the full set of course materials for the program. If you would like to purchase a binder, please indicate that below:

I am registering for the AMC Program and would like to purchase the binder for \$45



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1025 Connecticut Avenue, NW
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*Legal Issues Affecting
Academic Medical Centers and
Other Teaching Institutions*

January 21-22, 2010
Ritz-Carlton Hotel
Washington, DC

Register by December 30 and save!
For updates and to register, go to
www.healthlawyers.org/programs

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