

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions

Washington DC

January 25–26, 2007
The Ritz-Carlton Hotel



Planning Committee
Ivy Baer, Esq. – Co-Chair
Nancy E. Forbes, Esq. – Co-Chair
Julia S. Faber, Esq.
Edward B. Goldman, Esq.



*Huron Consulting Group has provided
sponsorship in support of this program.
In cooperation with the
Association of American Medical Colleges.*



Program Agenda

Thursday, January 25, 2007

7:30 am–5:45 pm

Registration and Information

8:15–10:45 am

GENERAL SESSION

8:15–8:30 am

Welcome and Introduction

Elisabeth Belmont, AHLA President-Elect

Ivy Baer, Program Co-Chair

Nancy E. Forbes, Program Co-Chair

8:30–9:30 am

Conflicts of Interest—Where are the Problems? What are the Solutions?

Ezekiel J. Emanuel

9:30–10:45 am

Raising Arizona: Growing Doctors and Biomedical Research through the University of Arizona College of Medicine Expansion

Beth Schermer

- Making the case for a second research based medical school campus to the legislature, the business community, local healthcare organizations – and within the medical school and the university
- Who's in charge: Working collaboratively with another university and with community research organizations
- The challenges of establishing hospital and faculty affiliations in a well-developed – and competitive – healthcare market
- Managing the opportunities and tensions of medical school expansion, including two campuses, faculty and administrative issues and funding
- A glimpse of the other side: Lessons learned as a lawyer suddenly serving as an administrator

CONCURRENT SESSIONS

11:00 am–12:00 noon

A. Public Health Law in Practice: Bioterrorism and Infectious Disease (not repeated)

Peter D. Jacobson

- Key legal questions in confronting a public health emergency
- Understanding a state's public health code

- Balancing individual and community rights
- Governmental “taking” of the facility
- Assessing model acts and state emergency preparedness plans
- Examining the role of the academic medical center's attorney

B. Determining Provider-Based Status and Impact on Medicare GME Payments

Gary W. Eiland

Karen S. Fisher

- CMS' approved process for Provider Status
- Criteria for on-campus and off-campus Provider-Based Status
- Weighing the relevant factors in deciding whether to pursue Provider Based Status
- Medicare DGME and IME Payments
 - Definition of a “hospital complex” for DGME resident count purposes
 - Non-hospital site policies
- Didactic time in resident FTE counts

C. Not-for-Profit and For-Profit Joint Ventures – What AMCs and Teaching Hospitals Need to Know

Veronica A. Marsich

Rachel Nosowsky

- Different forms of joint ventures and alternatives
- Legal issues that must be considered, with focus on Stark and Anti-Kickback Statute
- Special concerns for AMCs entering into (or exiting) contractual joint ventures
- Special concerns for research joint ventures

12:00 noon–1:30 pm

Lunch on your own or attend the Teaching Hospitals Practice Group Luncheon

Sponsored by Huron Consulting Group

(limited attendance; additional fee; pre-registration required; see page 11)

Patenting Life: Issues in Protection of Biological Materials

Michael J. Danksy (moderator)

Managing Director

Huron Consulting Group

Boston, MA

Dr. Lin Sun-Hoffman, PhD, JD

Applied Biosystems and Celera Group

Rockville, MD

Program Agenda

*Maximilian Grant, Esq.
Latham & Watkins LLP
Washington, DC*

1:40–2:55 pm **Extended Sessions**

D. Embryonic Stem Cell Research Oversight Committees (ESCROs) (not repeated)

*Susan H. Ehringhaus
Ann N. James
Jennifer Kulynych
Pearl O'Rourke*

- Who should have an ESCRO, and why?
- Is the IRB the best (or only) model for ESCRO operations?
- What is the current state of the NAS guidelines?
- Does compliance equal strict adherence to the NAS guidelines, or simply adoption of certain principles?
- What responsibilities are within the scope of the ESCRO? To what extent must it review compliance with applicable legal requirements (ranging from FDA tissue regulations to NIH cost principles to HIPAA and state law)?
- How should an institution set standards for ESCRO review of research, and how should these standards be operationalized?
- What responsibility should the ESCRO have to examine the provenance (i.e., circumstances of derivation) of hESC lines obtained from elsewhere?
- What considerations apply to the research use of excess fertility embryos, versus the derivation of embryos specifically for research?
- What resources are required to operate and provide administrative support to an ESCRO?

E. Enforcement of Federal Grant Accounting

*Diane Dean (invited)
Holley Thames Lutz
Rachel Nosowsky*

- Overview of relevant rules and regulations and NIHGPS provisions necessary for proper grant accounting
- Recent enforcement activities ranging from sub-contractor accountability such as the Yale subpoenas and FCA settlements related to time and effort, cost transfers, etc.
- Practical tips for compliance

F. Innovative Financial Arrangements with Faculty Physicians

*Eric B. Gordon
Max M. Reynolds*

- Faculty incentive compensation structures
- Shared clinical revenue ventures
- Equity joint ventures between the teaching hospital and faculty practice plan
- Shared ancillary arrangements
- Centers of excellence/under arrangements models

3:05–4:05 pm

G. Legalizing our DNA: The Rise of Genetic Databases (not repeated)

*Edward B. Goldman
Kristen B. Rosati*

Researchers, hospitals, and federal and state governments are creating genetic databases for research purposes. The genetic databases vary from proposed hospital databases of patient DNA profiles, to state cancer, trauma and newborn screening banks, to the National Cancer Institute's caBIG (the "cancer Biomedical Informatics Grid," a voluntary network connecting individuals and institutions to enable the sharing of data and tools for cancer research). This session will explore the legal implications of those databases including:

- Protecting participants' privacy
- Regulating access by third parties for public safety, insurance or other reasons
- Handling participants' rights to research findings with clinical significance
- Considering the rights of participants' family members
- Storing DNA for future unspecified research
- Commercializing "unidentified" DNA
- Complying with the HHS final rule on current good tissue practice for human cell, tissue and cellular and tissue-based product establishments

H. Legal Issues in the Negotiation of Clinical Study Agreements between Academic Medical Centers and Industry Sponsors

*Christopher Clark
Karen A. Mullin*

- Publication
- Confidentiality



Program Agenda

- Intellectual property
- Indemnification issues

J. Recruitment Assistance to Faculty and Medical Teams: Unique Arrangements and Issues for Academic Medical Centers

*Thomas S. Stukes, Sr.
J. McLain Wallace, Jr.*

- How the organization of the AMC affects structure and compliance issues
- The interplay of faculty practice plan compensation models and recruitment assistance under Stark and Anti-kickback Statutes assistance
- Alternatives to direct recruitment
- Satisfying IRS charitable purpose issues

4:15–5:30 pm *Extended Sessions*

K. Compliance Issues in Overseas Health and Research Projects (not repeated)

*Michele M. Garvin
Catherine L. Manzi*

- Legal issues in overseas projects: Contracts and MOUs, taxation, labor, human subjects research, corporate form and registration, Foreign Corrupt Practices Act, export controls, immigration and work permits, and other U.S. and foreign laws
- Practical considerations: Managing people, subcontractors, real estate, equipment (especially automobiles), supplies, and finances; local politics; currency issues; benefits and insurance (including evacuation insurance); security plans; shipment and storage issues; exit strategy
- The Federal Funds Overlay: OMB cost principles and administrative requirements, federal funding mechanisms, and specific agency policies (HHS)
- Putting the pieces together: Integration of “entrepreneurial” researchers into institutional compliance programs, key institutional stakeholders, internal processes/policies/procedures/systems/controls, pre-award project “capture” and input, oversight, and reporting

E. Enforcement of Federal Grant Accounting (repeat)

F. Innovative Financial Arrangements with Faculty Physicians (repeat)

5:30–6:30 pm

Reception

Sponsored by Huron Consulting Group
(attendees, speakers, and registered spouses and guests welcome)

Friday, January 26, 2007

7:00 am–3:40 pm

Registration and Information

7:00–8:30 am

Continental Breakfast

Sponsored by Huron Consulting Group
(attendees, speakers and registered spouses and guests welcome)

7:15–8:15 am

Legal and Corporate Ethics: Evolving Standards of Conduct in Academic Medical Centers

Jeffrey M. Scoryers

- Changing ethical standards within Academic Medical Centers
- Legal duties and ethical conflicts of interest in academic medicine
- Perceived and real conflicts of interest in academic medicine
- Extramural funding dilemmas – legal and ethical issues
- Developing and implementing corporate ethics guidelines including sample policies

GENERAL SESSION

8:30–9:00 am

Update from the OIG

Lewis Morris

9:00–10:30 am

States Tackling Health Care Reform

*Jamie Katz
Mark Reynolds*

Program Agenda

CONCURRENT SESSIONS

10:45–11:45 am

L. Special Subject Populations: Human Subject Research with Children, Prisoners, Pregnant Women and the Decisionally Impaired

(not repeated)

Kristina C. Borrer

Teresa J. Colecchia

- Federal regulations and policy—what are the general protections for all research and additional protections for vulnerable populations?
- Additional protections for pregnant women, human fetuses and neonates involved in research—what the HHS, FDA, and EPA regulations say, recent OHRP findings, and State law considerations
- Additional protections pertaining to research involving prisoners as subjects— what the HHS, FDA, and BOP regulations say, recent OHRP findings, and State law considerations
- Additional protections for children involved as subjects in research— what the HHS, FDA, and EPA regulations say, recent OHRP findings
- Additional DHHS protections for research subjects with decisional incapacities – what the HHS regulations say, basic principles, and State law considerations

M. Institutional/IRB Noncompliance and Research Misconduct

Karena J. Cooper

Julia Krebs-Markrich

- Analysis of OHRP determination letters
- Trends or differences in OHRP enforcement
- Overview of DHHS rules governing research misconduct
- Practical considerations for compliance

B. Determining Provider-Based Status and Impact on Medicare GME Payments (repeat)

11:45 am–1:15 pm

Lunch and Presentation

Sponsored by Huron Consulting Group
(attendees and speakers welcome)

Home Plate, the Cheese Lady and Bad Sonnets: On the Limitations of Regulation

Samuel Gorovitz

CONCURRENT SESSIONS

1:30–2:30 pm

N. Exposing and Examining Vendor Relationships

Kelly S. Curran

Ann N. James

- Industry practices and potential kickbacks
- AMA recommendations
- Industry and academic medical center policies
- State legislative initiatives
- Compliance planning considerations

C. Not-for-Profit and For-Profit Joint Ventures – What AMCs and Teaching Hospitals Need to Know (repeat)

M. Institutional/IRB Noncompliance and Research Misconduct (repeat)

2:40–3:40 pm

H. Legal Issues in the Negotiation of Clinical Study Agreements between Academic Medical Centers and Industry Sponsors (repeat)

J. Recruitment Assistance to Faculty and Medical Teams: Unique Arrangements and Issues for Academic Medical Centers (repeat)

N. Exposing and Examining Vendor Relationships (repeat)

Adjournment



Program Faculty

PLANNING COMMITTEE

Ivy Baer, Esq.

Program Co-Chair
Director and Regulatory Counsel
Association of American
Medical Colleges
Washington, DC

Nancy E. Forbes, Esq.

Program Co-Chair
Ropes & Gray LLP
Boston, MA

Julia S. Faber, Esq.

University Counsel
Office of General Counsel
Vanderbilt University
Nashville, TN

Edward B. Goldman, Esq.

Deputy General Counsel
University of Michigan Health System
Ann Arbor, MI

Kristina Borrer, PhD

Director of Compliance Oversight
Office of Human Resource Protection,
DHHS
Rockville, MD

Christopher Clark, Esq.

Partners Healthcare System, Inc.
Boston, MA

Theresa J. Colecchia, Esq.

Associate General Counsel, OGC
University of Pittsburgh
Pittsburgh, PA

Karena J. Cooper, JD, MSW

Division of Compliance Oversight,
Office of Human Research Protections,
DHHS
Rockville, MD

Kelly S. Curran, Esq.

Compliance Attorney
University of Pennsylvania Medical
School
Philadelphia, PA

Diane Dean (Invited)

Director, Division of Grants
Compliance and Oversight
National Institutes of Health
Bethesda, MD

Susan H. Ehringhaus, JD

Associate General Counsel for
Regulatory Affairs
Association of American Medical
Colleges
Washington, DC

Gary W. Eiland, Esq.

Vinson & Elkins LLP
Houston, TX

Ezekiel J. Emanuel, MD, PhD

Chief, Clinical Bioethics Department
National Institutes of Health
Bethesda, MD

Karen S. Fisher, JD

Senior Associate Vice President,
Healthcare Affairs
Association of American Medical
Colleges
Washington, DC

Michele M. Garvin, Esq.

Ropes & Gray LLP
New York, NY

Eric B. Gordon, Esq.

McDermott Will & Emery LLP
Los Angeles, CA

Samuel Gorovitz, PhD

Professor of Philosophy
Syracuse University
Syracuse, NY

Peter D. Jacobson, JD, MPH

Professor
University of Michigan
Ann Arbor, MI

Ann N. James, PhD, JD

University Senior Counsel
Stanford University Medical Center
Stanford, CA

Jamie Katz, Esq.

General Counsel
The Commonwealth of Massachusetts
Commonwealth Health Insurance
Connector Authority
Boston, MA

Julia Krebs-Markrich, Esq.

Reed Smith LLP
Falls Church, VA

Jennifer Kulynych, JD, PhD

Johns Hopkins Medicine
Baltimore, MD

Holley Thames Lutz, Esq.

Sonnenschein Nath &
Rosenthal LLP
Washington, DC

Catherine L. Manzi, Esq.

Office of the Secretary, Office of the
General Counsel
Public Health Division, National
Institutes of Health Branch
DHHS
Bethesda, MD

Veronica A. Marsich, Esq.

Smith Haughey Rice & Roegge
Ann Arbor, MI

Lewis Morris, Esq.

Chief Counsel to the Inspector General
US Department of Health and Human
Services
Washington, DC

Karen A. Mullin, JD, LLM

Boston University Medical Campus
Office of Research Administration
Boston, MA

Rachel Nosowsky, Esq.

Assistant General Counsel
University of Michigan
Ann Arbor, MI

Pearl O'Rourke, MD

Director of Human Affairs
Partners HealthCare System, Inc.
Boston, MA

Mark Reynolds

CEO
Neighborhood Health Plans of
Rhode Island
Providence, RI

Max M. Reynolds, Esq.

Health System Counsel
University of California
Oakland, CA

Kristen B. Rosati, Esq.

Coppersmith Gordon Schermer
Owens & Nelson PLLC
Phoenix, AZ

Beth Schermer, Esq.

Vice Dean, Administration
University of Arizona College of
Medicine
Phoenix, AZ

Jeffrey M. Sconyers, Esq.

Vice President and General Counsel
Children's Hospital and Regional
Medical Center
Seattle, WA

Thomas S. Stukes, Sr., Esq.

Womble Carlyle Sandridge
& Rice PLLC
Greensboro, NC

J. McLain Wallace, Jr., Esq.

Vice President, Legal Affairs
North Carolina Baptist Hospital
Winston-Salem, NC

Program at a Glance

Thursday, January 25, 2007

7:30 am– 5:30 pm	Registration and Information		
8:15– 10:45 am	<p>General Session 8:15–8:30 am Welcome and Introduction <i>Baer, Belmont, Forbes</i></p> <p>8:30–9:30 am Conflicts of Interest—Where are the Problems? What are the Solutions? <i>Emanuel</i></p> <p>9:30–10:45 am Raising Arizona: Growing Doctors and Biomedical Research Through the University of Arizona College of Medicine Expansion <i>Schermer</i></p>		
11:00 am– 12:00 noon	<p>A. Public Health Law in Practice: Bioterrorism and Infectious Disease (not repeated)</p> <p><i>Jacobson</i></p>	<p>B. Determining Provider-Based Status and Impact on Medicare GME Payments</p> <p><i>Eiland Fisher</i></p>	<p>C. Not-for-Profit and For-Profit Joint Ventures – What AMCs and Teaching Hospitals Need to Know</p> <p><i>Marsich Nosowsky</i></p>
12:00 noon– 1:30 pm	<p>Lunch on your own or attend the Teaching Hospitals Practice Group Luncheon <i>Sponsored by Huron Consulting Group</i> (limited attendance; additional fee; pre-registration required; see page 11)</p>		
1:40– 2:55 pm extended sessions	<p>D. Embryonic Stem Cell Research Oversight Committees (ESCROs) (not repeated)</p> <p><i>Ehringhaus James Kulynych O'Rourke</i></p>	<p>E. Enforcement of Federal Grant Accounting</p> <p><i>Dean (invited) Lutz Nosowsky</i></p>	<p>F. Innovative Financial Arrangements with Faculty Physicians</p> <p><i>Gordon Reynolds</i></p>
3:05– 4:05 pm	<p>G. Legalizing our DNA: The Rise of Genetic Databases (not repeated)</p> <p><i>Goldman Rosati</i></p>	<p>H. Legal Issues in the Negotiations of Clinical Study Agreements between AMCs and Industry Sponsors</p> <p><i>Clark Mullin</i></p>	<p>J. Recruitment Assistance to Faculty and Medical Teams: Unique Arrangements and Issues for Academic Medical Centers</p> <p><i>Stukes Wallace</i></p>
4:15– 5:30 pm extended sessions	<p>K. Compliance Issues in Overseas Health and Research Projects (not repeated)</p> <p><i>Garvin Manzi</i></p>	<p>E. Enforcement of Federal Grant Accounting (repeat)</p> <p><i>Dean (invited) Lutz Nosowsky</i></p>	<p>F. Innovative Financial Arrangements with Faculty Physicians (repeat)</p> <p><i>Gordon Reynolds</i></p>
5:30– 6:30 pm	<p>Reception <i>Sponsored by Huron Consulting Group</i> (attendees, speakers, and registered spouses and guests welcome)</p>		

Program at a Glance

Friday, January 26, 2007

7:00 am– 3:40 pm	Registration and Information		
7:00– 8:30 am	Continental Breakfast <i>Sponsored by Huron Consulting Group</i> (attendees, speakers and registered spouses and guests welcome)		
7:15– 8:15 am	Legal and Corporate Ethics: Evolving Standards of Conduct in Academic Medical Centers <i>Sconyers</i>		
8:30– 10:30 am	General Session 8:30–9:00 am Update from the OIG <i>Morris</i> 9:00-10:30 am States Tackling Health Care Reform <i>Jamie Katz, Mark Reynolds</i>		
10:45– 11:45 am	L. Special Subject Populations: Human Subject Research with Children, Prisoners, Pregnant Women and the Decisionally Impaired (not repeated) <i>Borror Colecchia</i>	M. Institutional/IRB Noncompliance and Research Misconduct <i>Cooper Krebs-Markrich</i>	B. Determining Provider-Based Status and Impact on Medicare GME Payments (repeat) <i>Eiland Fisher</i>
11:45 am– 1:15 pm	Lunch and Presentation <i>Sponsored by Huron Consulting Group</i> (attendees and speakers welcome) Home Plate, the Cheese Lady and Bad Sonnets: On the Limitations of Regulation <i>Gorovitz</i>		
1:30– 2:30 pm	N. Exposing and Examining Vendor Relationships <i>Curran James</i>	C. Not-for-Profit and For-Profit Joint Ventures – What AMCs and Teaching Hospitals Need to Know (repeat) <i>Marsich Nosowsky</i>	M. Institutional/IRB Noncompliance and Research Misconduct (repeat) <i>Cooper Krebs-Markrich</i>
2:40– 3:40 pm	H. Legal Issues in the Negotiations of Clinical Study Agreements between AMCs and Industry Sponsors (repeat) <i>Clark Mullin</i>	J. Recruitment Assistance to Faculty and Medical Teams: Unique Arrangements and Issues for Academic Medical Centers (repeat) <i>Stukes Wallace</i>	N. Exposing and Examining Vendor Relationships (repeat) <i>Curran James</i>

Hotel Reservation Form American Health Lawyers Association

Legal Issues Affecting Academic Medical Centers & Other Teaching Institutions

January 25-26, 2007

The Ritz-Carlton, Washington, DC
1150 22nd Street, NW
Washington, DC 20037

Please complete the information requested below and fax to 202-974-5519 by January 8, 2007. If you would like to receive written confirmation, please provide an e-mail address. Reservations can also be made online by going to www.ritzcarlton.com and selecting the "Reservations" link at the top of the page. After choosing Washington D.C. as the preferred hotel, select your desired dates and enter AHLAHLA in the "Group Code" field at the bottom of the window. If you prefer to speak to a reservation agent, please call 1-800-241-3333 and identify yourself as being with the American Health Lawyers Association.

Name: (Dr/Mr/Mrs/Ms) _____

Company: _____

Address: _____

City: _____ State: _____

Zip/Postal Code: _____ Country: _____

Phone: _____ Email: _____

The group rate of \$230 per night is available until the group cut-off date of January 8, 2007, or the contracted room block is filled, whichever comes first. All room rates are subject to applicable local tax currently 14.5% per room per night. Standard check-in time is 3:00pm, standard check-out time is 12:00 (noon). Guaranteed early arrivals (prior to 3:00pm) need to be reserved for the night before and will be charged accordingly. Early arrival or late departure booked on space-available basis.

Arrival Date: _____ Arrival Time: _____

Departure Date: _____ Departure Time: _____

Non-Smoking Deluxe Room (1 King Bed) @ \$230.00 per night

Non-Smoking Deluxe Room (2 Double Beds) @ \$230.00 per night

Special Needs: _____

All attendees are required to submit a credit card number to guarantee their reservations. In the event the individual no-shows, the credit card will be charged one night's room & tax. Hotel cancellation policy states that cancellations must be made before 12:00 noon, day of arrival.

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Credit Card Number: _____ Exp. Date: _____

Card Holder's Name: _____

Card Holder's Signature: _____

Program Information

Dates: January 25-26, 2007
Place: The Ritz-Carlton Hotel
1150 22nd Street, NW
Washington, DC 20037
Phone: (202) 835-0500
Fax: (202) 835-1588

Registration Fees:
Postmarked and paid by January 8

\$690 For the first AHLA Member
\$615 For each additional Member
\$890 Non-Members

Postmarked and paid between January 9 and January 18*

\$790 For the first AHLA Member
\$715 For each additional Member
\$1090 Non-Members

* Registration fees increase \$100 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) 833-0766 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 12.75 continuing education credits (including 1.0 ethics credit) based on a 60-minute hour and 15.3 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. Web site: www.nasba.org. This seminar will be worth approximately 15.0 CPE credits.

There are no prerequisites or advanced preparations required to register for this group live program. Sessions are intermediate unless otherwise indicated.

Hotel Reservations: Hotel accommodations are not included in the registration fee. Call the Ritz-Carlton Hotel (202) 974-5519 or use the reservation form found on page 9. ***If calling, please indicate that you are attending the AHLA program. Rooms at the group rate are limited and may sell out.***

Membership: Dues are \$175 for those admitted to the Bar/graduated from college within the last four years; \$295 for those admitted/ graduated more than four but less than eight years ago; and \$335 for those admitted/graduated eight or more years ago. Dues are \$150 (or \$75 for electronic benefits) for government employees and full-time academicians; and \$25 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 17, 2007.*** 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) 833-0766. Please note that registration fees are based on the AHLA membership status of the individual who actually attends the program.

Special Needs: If you need any of the auxiliary aids or services identified in the Americans with Disabilities Act, please call the Member Service Center at (202) 833-0766.

Travel: Association Travel Concepts (ATC) has negotiated discounts with United, American, Enterprise and Avis Rental Car to bring you special fares and car rental rates lower than those available to the public. Discounts apply for travel January 19-29, 2007. For tickets purchased less than 30 days prior, the discounts will be 5% to 15% off of the lowest available fares. Some restrictions may apply and a service fee may apply. ATC will also search for the lowest available fare on any airline.

ASSOCIATION TRAVEL CONCEPTS

1-800-458-9383

email: reservations@atcmeetings.com

www.atcmeetings.com

(follow the Member Travel links)

Fax: (858) 362-3153

ATC is available for reservations from 9:00 am until 7:30 pm Eastern, Monday through Friday.

Registration Form: Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions

3

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.

Name: _____ Member ID #: _____

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

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Early Registration Fees (faxed/postmarked and paid on or before January 8, 2007):

- AHLA/AAMC Members:** \$690 **Non-Members:** \$890
 \$615 each additional AHLA/AAMC member registering from same organization at same time on the same check or credit card payment

Registration Fees (faxed/postmarked and paid between January 9 and January 18, 2007):

- AHLA/AAMC Members:** \$790 **Non-Members:** \$1090
 \$715 each additional AHLA/AAMC member registering from same organization at same time on the same check or credit card payment

Special Offer for Program attendees! Purchase the AHLA Program on CD from the AMC program (contains detailed, searchable, and linked index, AUDIO as well as materials from every session)—**\$99***

* All orders will be fulfilled 4-6 weeks after the program.

Or if you can't attend the program but would like to purchase a CD of the program materials

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions, Item #26710-10
 Members \$199/Non-Members \$259 \$ _____

(shipping and handling will be added; 6% tax will be added for PA residents; 5.75% tax will be added for DC residents)

PAYMENT INFORMATION

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

\$ _____ Registration Fee

\$ _____ Teaching Hospitals Practice Group Luncheon (\$38 for members of the Teaching Hospitals PG/\$43 for non-members of the Teaching Hospitals PG; Thursday, January 25, 2007)

\$ _____ Academic Medical Centers CD

\$ _____ 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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Signature of Cardholder: _____

ZIP Code of Cardholder's Billing Address _____

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 17, 2007. Please see p. 10 of this brochure for AHLA's full refund policy.



AMERICAN
HEALTH LAWYERS
ASSOCIATION

1025 Connecticut Avenue, NW
Suite 600
Washington, DC 20036-5405

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions

Washington, DC

January 25-26, 2007
The Ritz-Carlton Hotel

Register by January 8, 2007 and save!
Register online today at
www.healthlawyers.org/programs

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