

AHLA

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions

January 23-24, 2014 | Ritz-Carlton Hotel | Washington, DC

Co-sponsored with National Association of
College and University Attorneys (NACUA)
and Association of American Medical
Colleges (AAMC)



*PYA has provided sponsorship
in support of this program.*

Planning Committee:

Ann T. Hollenbeck, Program Co-Chair
Jeff Sconyers, Program Co-Chair
Ann N. James
Holley Thames Lutz
Heather H. Pierce
Stephen D. Sencer

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions

Program Agenda

Thursday, January 23, 2014

7:00 am-5:15 pm	Registration and Information
General Session 8:00-8:15 am	Welcome and Introduction <i>Peter A. Pavarini, AHLA President-Elect</i> <i>Ann T. Hollenbeck, Program Co-Chair</i> <i>Jeff Sconyers, Program Co-Chair</i>
8:15-8:45 am	Keynote Address <i>Atul Grover</i>
8:45-9:15 am	SUPPORT: Legal and Ethical Issues in Clinical Effectiveness Research <i>Michele K. Russell-Einhorn</i>
9:15-10:45 am	<i>Paul B. Costello (Moderator)</i> <i>Michael Carome</i> <i>Nancy Kass</i> <i>John Lantos</i> SUPPORT—the Surfactant Positive Airway Pressure and Pulse Oximetry Trial—was an NIH-funded multi-center study of the clinical effectiveness of two different protocols for high-risk premature neonates. Researchers intended this clinical effectiveness study to provide evidence to support, contradict or modify established standard management techniques for these babies. Major questions have since been raised about the ethics of the study: whether parents enrolling their children were adequately informed of the risks, whether the study involved experimental treatment at all, and more broadly how to conduct clinical effectiveness research in the future. Supporters say that without studies like SUPPORT, we will never know if “standard” care actually helps or harms patients; critics say that SUPPORT and trials like it create unacceptable risks and lack full disclosure. This session will begin with a review of the factual, legal, regulatory and ethical issues raised by SUPPORT and other clinical effectiveness research. Then a distinguished panel, representing all sides of the debate, will discuss the issues and how teaching hospitals, academic medical centers and investigators should think about them. This should be a lively and interactive session and provide much food for thought, as well as guidance for legal advice.
10:45-11:00 am	Break, sponsored by PYA
11:00 am-12:00 noon	Year in Review <i>Elizabeth Carder-Thompson</i>
12:00 noon-1:20 pm	Lunch on your own or attend the Teaching Hospitals and Academic Medical Centers Practice Group Luncheon, sponsored by PYA (limited attendance; additional fee; pre-registration required; see page 11) Organ Allocation Meets the Judicial System: Thoughts on the Sarah Murnaghan Lung Allocation Case <i>Stephen G. Harvey, Pepper Hamilton LLP, Philadelphia, PA</i>
CONCURRENT SESSIONS 1:30-2:30 pm	A. Advising on Media Relations (not repeated) <i>Paul B. Costello</i> <i>William W. Horton</i> <i>Gina Vild</i> <ul style="list-style-type: none">• Journalists’ expectations and advice on how to frame complicated messages for a lay audience• How media relations and the office of general council can work effectively together on complex communications issues including strategies and interactions with the press B. Health Care Reform and Academic Medical Centers: How to Thrive in a Changing Environment <i>Troy Barsky</i> <i>Sarah J. DiBoise</i> <ul style="list-style-type: none">• The most important health care reform initiatives that impact academic medical centers (AMCs) such as changes in health care payment, accountable care organizations and increased fraud and abuse risk and enforcement

Program Agenda

Thursday, January 23, 2014 (continued)

CONCURRENT SESSIONS

(Continued)

1:30-2:30 pm

- The unique attributes of AMCs that increase their chances of success in a new health care environment
- The challenges that AMCs face because of health care reform with a focus on business arrangements, governance, and their research and education mission
- Recent developments in AMC joint ventures with community hospitals including the movement towards accountable care and risk based payments
- What might the future hold: Increased risk but greater potential for reward?

C. Age-Based Policies for Physician Faculty—Legal and Practical Challenges*Richard D. Barton**Dorothy A. Brown*

The literature and public scrutiny of the issue of advancing clinician age and its impact on clinical performance has forced medical centers to examine their policies and approaches to detecting and addressing cognitive and physiologic decline. This effort has brought the hospital industry face to face with the complex web of federal and state laws and regulations which require oversight of quality of care and patient safety, yet prohibit age and disability discrimination. This issue is even more complicated for Academic Medical Centers due to the rules regarding tenured faculty. This presentation will examine

- The literature addressing the impact of age on clinical performance
- The legal requirement to monitor physician performance and address impairment
- The evolution of age and disability discrimination laws and their application in industries impacting public safety
- Tenure and its impact on addressing declining clinical performance
- Identifying and managing declining competence—existing policies and practices
- The practical challenges in the implementation of age-based policies

2:45-3:45 pm

D. Academic Medical Centers/Teaching Hospitals and Rural Health Care Affiliations: Legal Opportunities and Challenges (not repeated)*Jan E. Murray**Anne F. Strassfeld*

- The shape of rural health care delivery: Critical access hospitals, sole community hospitals, rural referral centers, Medicare-dependent hospitals
- The rapid growth in a variety of affiliations between AMC/THs and rural health care providers, drivers of affiliations (need for expertise, economic pressure on rural health facilities) and range of affiliation options (acquisition, joint ventures, consulting/management of services or whole hospital, provision of services via telemedicine)
- Common legal issues in AMC/TH/rural health care affiliations: Anti-Kickback, reimbursement, other situational applications: Antitrust, state regulation, tax-exemption
- Legal opportunities for working with rural health care providers: Rural health care exceptions or favorable treatment in many regulatory areas including: Anti-Kickback, ACOs, GME, antitrust, reimbursement
- Special issues: Working with government-owned facilities such as county hospitals

E. Big Data, Big Promise and (Potentially) Big Problems*Kent Bottles**Kristen B. Rosati*

With the migration to electronic health records, the health care industry is about to jump head-first into the “Big Data” pool. Big Data attempts to extract new insights and create new forms of value by analyzing large data sets to find actionable correlations. Big Data’s focus on correlations, not causality established by hypothesis driven clinical trials, can be difficult for physicians and others trained in the biomedical model where the focus is finding the cause of disease in order to treat it. But Big Data has the potential to improve health services research and the public health, shorten the drug development pipeline by reforming how we

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Program Agenda

Thursday, January 23, 2014 (continued)

2:45-3:45 pm (continued)	<p>conduct clinical trials, and reduce the cost of health care. At the same time, Big Data poses serious challenges to patient privacy that outstrip our current laws.</p> <ul style="list-style-type: none">• What Big Data is and how it applies to health care delivery, research, and treatment• How actionable correlations are different than hypothesis driven causality and why it is important for medicine• How Big Data can help academic medical centers decrease per-capita cost, increase quality, and adjust to the transition from fee for service to global, value-based payments systems• How Big Data creates challenges to patient privacy and likely developments in de-identification, re-identification, and genetic privacy• When the use of Big Data for quality improvement and other internal health care operations becomes “research” that requires IRB review <p>F. 2014 Fraud and Abuse Update for AMCs <i>Lisa M. Ohrin</i> <i>Robert A. Wade</i></p> <ul style="list-style-type: none">• Is the Stark Law AMC exception useful or a dinosaur?• Recent cases, settlements and investigations regarding AMCs• Recent developments regarding the Stark Law, Anti-Kickback Statute, and False Claims Act related to AMCs• AMC compensation models, including fair market value/commercial reasonableness and productivity and value-based models
4:00-5:00 pm	<p>G. GME: Everything You Always Wanted to Know about Medicare Medical Education Payments but Were Afraid to Ask Your Reimbursement Manager (not repeated) <i>Kenneth R. Marcus</i> <i>Lori K. Mihalich-Levin</i></p> <ul style="list-style-type: none">• Applications for resident slots is projected to exceed capacity• Limits on Medicare payment• Litigation challenging Medicare payment limitation• Update on resident slot redistribution• New rules on resident training at critical access hospitals• Strategies for coping <p>H. When Bad Things Happen in Good Research <i>George H. Mernick, III</i> <i>David Shuey</i></p> <p>Clinical research leads to advances in patient care, but can also lead to claims and litigation when research participants are injured as a result of a clinical trial.</p> <ul style="list-style-type: none">• The claims that have been made against teaching hospitals and academic medical centers for injuries occurring during clinical research• The outcome of those claims, insurance products that may be available to protect against such claims• The appropriate allocation of risks for injuries in agreements with clinical trial sponsors <p>J. Legal Ethics when It's All (Sort of) Illegal: Advising Clients in the Health Care Wonderland <i>William W. Horton</i> <i>Jeff Sconyers</i></p> <ul style="list-style-type: none">• “Assuming it's not illegal, it's legal”: Legal advice when the devil is in the assumptions• “But how will the OIG find out?”: Advising the not-so-risk-averse client• “I'm just the lawyer”: Professional responsibility, personal integrity, and enlightened self-interest
5:00-6:00 pm	<p>Networking Reception sponsored by PYA (attendees, speakers, and registered spouses and guests welcome)</p> <p>Meet Your Colleagues—All attendees are welcome to take part in the 8-Minute Speed Networking activity during the reception</p>

Program Agenda

Friday, January 24, 2014

7:00 am-3:15 pm	Registration and Information
7:00-8:30 am	Continental Breakfast <i>sponsored by PYA</i> (attendees, speakers and registered spouses and guests welcome)
Concurrent Sessions 8:30-9:30 am	<p>K. Masters Class: Religious Directives vs. AMC Mission (not repeated) (pre-registration required; space is limited; see page 11) <i>Rev. William P. Grogan</i> <i>Ann T. Hollenbeck</i> <i>Jane Jordan</i> <i>Lawrence E. Singer</i></p> <ul style="list-style-type: none"> • This Master's-level session is designed to cover advanced topics in an interactive, roundtable format that assumes a sophisticated level of knowledge on the subject of the program • Discussion leaders will present scenarios from their transactional experiences • Actual contract provisions and their practical impact will be discussed <p>L. Your Insulin Pump Just Started My Car: Security Issues in Medical Devices, Social Media Use in Health Care and Other Technologies that Go Bump in the Night <i>Marti Arvin</i> <i>Melissa L. Markey</i></p> <p>New uses, sources and locations of data create new legal challenges. This session will describe some of the more complex challenges posed by new technology, some traditional and non-traditional approaches to analyzing risks and responses, and a bit of crystal ball-gazing on what the future might hold as health care seeks to embrace the promise of big data without losing sight of the importance of privacy and security.</p> <ul style="list-style-type: none"> • BYOD—is it bring your own device, or bring your own disaster? • Cloud—stormy, or mostly sunny? • Data on departure—is health care at risk of economic espionage? • Social media, texting and non-traditional communications—Y cn't I txt? • Mobile medical devices—to regulate, or not to regulate, that is the question... <p>M. When It Rains It Pours: Best Practices for Managing Parallel Internal Investigations of Research-Related Misconduct or Noncompliance <i>Emily Fogler</i> <i>Kate Gallin Heffernan</i></p> <ul style="list-style-type: none"> • The various institutional officials, oversight bodies, policies and processes that may be implicated by research-related misconduct or noncompliance • Effective negotiation techniques with external stakeholders related to such investigations • The ways in which the requirements and standards applicable to, and the interests of, different institutional officials and oversight bodies may overlap or be in tension • Appropriate roles for individuals and oversight boards, including in-house counsel, involved in these processes • Pointers for responding to unique challenges presented when the research-related misconduct or noncompliance being internally investigated is related to an active government enforcement investigation or civil suit • Responding to government requests for information and investigations • Best practices for coordinating and conducting parallel investigations in a way that maximizes efficiency but also maintains the integrity and independence of each process • Case studies to further participants' understanding of how to manage parallel investigations and implement best practices at their own institutions <p>N. Enforcement Initiatives Relating to Federal Research Grants <i>Fara Damelin</i> <i>Paul W. Shaw</i></p> <ul style="list-style-type: none"> • Current enforcement trends by federal research funding agencies such as the National Science Foundation and NIH • "Hot button issues": Time and effort reporting, cost transfers, and cost allocation

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Friday, January 24, 2014 (continued)

Concurrent Sessions 8:30-9:30 am (continued)	<ul style="list-style-type: none"> The role of the NSF and HHS Inspector Generals in overseeing federal grant compliance Potential administrative, civil, and criminal liability for grant submissions How to safeguard your institution
9:45-10:45 am	<p>O. AMC's Go Global: How Can it Happen and What Does it Mean? (not repeated) <i>Jeffrey D. Kahn</i> <i>Michael B. Lambert</i></p> <ul style="list-style-type: none"> For AMCs, "international activities" cover a broad landscape. Some activities never leave a hospital's or school's own walls. Others put buildings and personnel thousands of miles away. For example: <ul style="list-style-type: none"> –Patients from outside the US come to US facilities for care –Staff from AMCs in the US practice at charitable or mission-based clinics in developing countries –AMCs develop educational cooperatives with institutions in other countries, ranging from observerships to full-blown programs –Clinical and administrative staff consult for institutions in other countries to develop their own facilities –AMCs develop joint ventures in other countries with international partners This session will address different kinds of international activities in which AMCs may engage, and the issues that those activities present for counsel <p>P. Implications of the Sunshine Act for Academic Medical Centers: Manufacturer-Physician Relationships under the Microscope <i>Jolee Hancock Bollinger</i> <i>Andrew D. Ruskin</i></p> <ul style="list-style-type: none"> Background on Sunshine Act and other financial conflict of interest regulatory schemes Implications of the Sunshine Act on business relationships with physician owned distributorships Billing compliance issues associated with use by physicians of investigational devices that are not disclosed to hospital Need for well-established conflict of interest disclosure and oversight, patient disclosure, and compliance processes How to implement with employed physicians <p>H. When Bad Things Happen in Good Research (repeat)</p>
11:00 am-12:00 noon	<p>B. Health Care Reform and Academic Medical Centers: How to Thrive in a Changing Environment (repeat)</p> <p>E. Big Data, Big Promise and (Potentially) Big Problems (repeat)</p> <p>J. Legal Ethics when It's All (Sort of) Illegal: Advising Clients in the Health Care Wonderland (repeat)</p>
12:00 noon-1:15 pm	<p>Lunch on your own or attend the Life Science and Tax and Finance Practice Group Joint Luncheon (limited attendance; additional fee; pre-registration required; see page 11)</p>
CONCURRENT SESSIONS 1:30-2:30 pm	<p>C. Age-Based Policies for Physician Faculty—Legal and Practical Challenges (repeat)</p> <p>M. When It Rains It Pours: Best Practices for Managing Parallel Internal Investigations of Research-Related Misconduct or Noncompliance (repeat)</p> <p>N. Enforcement Initiatives Relating to Federal Research Grants (repeat)</p>
2:45-3:45 pm	<p>F. 2014 Fraud and Abuse Update for AMCs (repeat)</p> <p>L. Your Insulin Pump Just Started My Car: Security Issues in Medical Devices, Social Media Use in Health Care and Other Technologies that Go Bump in the Night (repeat)</p> <p>P. Implications of the Sunshine Act for Academic Medical Centers: Manufacturer-Physician Relationships under the Microscope (repeat)</p>

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Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions

Program-At-A-Glance

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7:00 am- 5:15 pm	Registration and Information		
8:00 am- 12:00 noon	<p>GENERAL SESSION</p> <p>8:00-8:15 am Welcome and Introduction <i>Pavarini, Hollenbeck, Sconyers</i></p> <p>8:15-8:45 am Keynote Address <i>Grover</i></p> <p>SUPPORT: Legal and Ethical Issues in Clinical Effectiveness Research</p> <p>8:45-9:15 <i>Russell-Einhorn</i></p> <p>9:15-10:45 am <i>Costello (Moderator), Carome, Kass, Lantos</i></p> <p>10:45-11:00 am Break, sponsored by PYA</p> <p>11:00 am-12:00 noon Year in Review <i>Carder-Thompson</i></p>		
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2:45- 3:45 pm	<p>D. Academic Medical Centers/Teaching Hospitals and Rural Health Care Affiliations: Legal Opportunities and Challenges (not repeated)</p> <p><i>Murray Strassfeld</i></p>	<p>E. Big Data, Big Promise and (Potentially) Big Problems</p> <p><i>Bottles Rosati</i></p>	<p>F. 2014 Fraud and Abuse Update for AMCs</p> <p><i>Ohrin Wade</i></p>
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Program Information

Dates: January 23-24, 2014

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

Phone: (202) 835-0500

Reservations: (800) 241-3333

Registration Fees:

Postmarked and paid by January 10, 2014

\$695 For the first AHLA/AAMC/NACUA Member

\$620 For each additional Member

\$920 Non-Members

Postmarked and paid between January 11-19, 2014*

\$820 For the first AHLA/AAMC/NACUA Member

\$745 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 11.0 continuing education credits (including 1.0 ethics credit) based on a 60-minute hour and 13.2 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 13.0 CPE credits.

This program is designed to be an update on developments in the area of 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 the area of AMCs 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 at (202) 835-0500. ***If calling, please indicate that you are attending the AHLA program. Rooms at the group rate of \$265 single/double occupancy are limited and may sell out prior to January 10, 2014.***

Membership: Dues are \$200 for those admitted to the Bar/graduated from college within the last four years; \$330 for those admitted/ graduated between four and eight years ago; and \$365 for those admitted/graduated eight or more years ago. Dues are \$110 for government employees and full-time academicians; \$90 for paralegals, \$160 for public interest professionals and \$35 for full-time law school students. 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, 2014***. 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 (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.

Learning Objectives:

- Increase knowledge of the legal and regulatory issues unique to AMCs and teaching hospitals
- Gain a greater understanding of the strategic challenges facing AMCs and teaching hospitals
- Learn about recent legal developments, cases, and trends

Academic Medical Centers Registration Form

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) 833-1100, 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: _____

City: _____ State: _____ ZIP+ 4: _____

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

E-Mail: _____

Spouse/Guest Name _____

I am a member of:

- AHLA NACUA AAMC

Early Registration Fees (faxed/postmarked and paid on or before January 10, 2014):

AHLA/NACUA/AAMC Members: \$695 **Non-Members:** \$920

Group Members: \$620 each additional AHLA/NACUA/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 11–January 19, 2014):

AHLA/NACUA/AAMC Members: \$820 **Non-Members:** \$1045

Group Members: \$745 each additional AHLA/NACUA/AAMC member registering from same organization at same time on the same check or credit card payment

- Masters Class: Religions Directives vs. AMC Mission, Friday, January 24, 8:30–9:30 am (limited to 20)

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

\$ _____ TH/AMC Practice Group Luncheon (\$35 for members of the TH/AMC PG/\$45 for non-members of the TH/AMC PG; Thursday, January 23, 2014)

\$ _____ Life Sciences and Tax and Finances Practice Group Joint Luncheon (\$35 for members of the Life Sciences/Tax PG; \$45 for non-members of the Life Sciences/Tax PG; Friday, January 24, 2014)

\$ _____ 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:     Diners Club

Number: _____ Exp. Date: /

Name of Cardholder: _____

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, 2014.

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

AHLA

1620 Eye Street, NW
6th Floor
Washington, DC 20006-4010

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