Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions

January 22-23, 2015 | Ritz-Carlton Hotel | Washington, DC

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

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

Program and Teaching Hospitals and Academic Medical Centers and Health Information and Technology Practice Group Luncheon Sponsor

Exhibitors
Huron Consulting Group
PYA

eProgram
All attendees will receive a complimentary copy of the Academic Medical Centers eProgram. The eProgram includes:

- Detailed Table of Contents
- Access to the complete list of program materials (PowerPoint presentations, outlines, supplemental materials, and checklists) (PDF files)
- Audio recordings of each session (mp4 files)

Live Tweet the Program Using #AHLA15

Will you be in Washington, DC for the Academic Medical Centers program? We encourage you to live tweet and include hash tag #AHLA15 so that attendees can learn from more than one session at once, and so that members unable to attend still feel plugged in. Would you like to live tweet one or more sessions of the program from a Practice Group Twitter handle? If so, please email Brian Davis bdavis@healthlawyers.org.
## Program Agenda

### Thursday, January 22, 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>7:00 am-5:30 pm</td>
<td>Registration and Information</td>
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<tr>
<td>8:00-8:15 am</td>
<td><strong>Welcome and Introduction</strong>&lt;br&gt;Lois D. Cornell, AHLA President-Elect&lt;br&gt;Ann T. Hollenbeck, Program Planning Co-Chair&lt;br&gt;Jeff Sconyers, Program Planning Co-Chair</td>
</tr>
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<td>8:15-8:45 am</td>
<td><strong>Keynote Address: The View from Inside the Beltway: Academic Medicine and the 114th Congress</strong>&lt;br&gt;Len Marquez</td>
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<td>8:45-9:45 am</td>
<td><strong>What Our Academic Medical Center Learned from Ebola</strong>&lt;br&gt;Susan Grant&lt;br&gt;Jane E. Jordan</td>
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<td>9:45-10:00 am</td>
<td>Break</td>
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<td>10:00-11:15 am</td>
<td><strong>How Do We Continue to Teach and Treat</strong>&lt;br&gt;Deborah W. Davis&lt;br&gt;Rachel Nosowsky&lt;br&gt;Andrew A. Ziskind</td>
</tr>
<tr>
<td>11:15 am-12:15 pm</td>
<td><strong>Year in Review</strong>&lt;br&gt;Elizabeth B. Carder-Thompson&lt;br&gt;It's been another banner year for health care developments affecting academic medical centers, from massive fraud and abuse investigative and enforcement initiatives, to ongoing health reform challenges, to dizzying developments in the world of reimbursement. Highlights of this fast-paced review will cover:&lt;br&gt;- This year’s colorful crop of <em>qui tam</em> relators&lt;br&gt;- What’s an excessive False Claims Act fine?&lt;br&gt;- When can regulatory non-compliance turn into a false claim?&lt;br&gt;- Are internal compliance investigations privileged?&lt;br&gt;- New OIG initiatives and issuances, including a laboratory payment Special Fraud Alert&lt;br&gt;- Kickback settlements by universities, hospitals, manufacturers, and more&lt;br&gt;- Challenges to the Two Midnight rule&lt;br&gt;- Hackers, laptop thefts, unencrypted hospital backup tapes, and other minefields for health care institutions</td>
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<td>12:15 noon-1:30 pm</td>
<td>Lunch on your own or attend the Teaching Hospitals and Academic Medical Centers and Health Information and Technology Practice Group Luncheon, sponsored by PYA&lt;br&gt;(limited attendance; additional fee; pre-registration required; see page 15)</td>
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<td>1:45-2:45 pm</td>
<td><strong>A. Built to Last: Anatomy of a Successful Public-Private Partnership between an AMC and Community Specialty Hospital</strong>&lt;br&gt;H. Guy Collier&lt;br&gt;Deborah W. Davis&lt;br&gt;- VCU Health System-Children's Hospital of Richmond affiliation: Project timeline and process employed to keep the transaction moving and on schedule</td>
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| 1:45-2:45 pm  | **B. Legal Ethics: Is Your Attorney-Client Privilege as Robust as You Think?**  
Michael E. Paulhus  
Mina Rhee  
• How recent precedents may expand or narrow the scope of privilege or work product protection in the context of health care litigation and investigations  
• Particular privilege concerns arising in the context of the federal Anti-Kickback Statute and the Stark Law, including a discussion of the crime-fraud exception to the attorney-client privilege  
• Government perspectives on FCA defendants' assertion of privilege  
• Best practices on how to protect and assert privilege  
• Privilege and ABA Model Rule 1.6 Duty of Confidentiality |
| 3:00-4:15 pm  | **C. Big Data, Cloud Computing and the New World Order for Health Care Privacy**  
Marti Arvin  
Kirk J. Nahra  
Teaching hospitals and academic medical centers create, use and supply vast amounts of data from a growing range of sources in the course of their clinical care and clinical research, and increasingly are housing that data with others, including in the “cloud.”  
• How health care companies are using personal data in and out of the HIPAA rules as a business imperative  
• How cloud computing is changing the environment for the privacy and security of personal data  
• How the growth of “non-HIPAA” health care data is creating a new paradigm for health care privacy regulation |
| 3:00-4:15 pm  | **D. Maintaining Independence through Interdependence—Alliances between AMCs and Community Hospitals**  
Jeffrey O. Ellis  
Robert Moser  
Daniel W. Peters  
Mark R. Thompson  
• The advantages to an AMC of pursuing alliances  
• The key characteristics of community hospital alliances  
• Options for governance structures  
• Common legal issues facing such alliances, including antitrust concerns  
• Practical advice regarding potential pitfalls and keys to success |
| 3:00-4:15 pm  | **E. Legal Ethics: Who Owns Compliance in an AMC/University?**  
Professional Responsibility and Organizational Considerations  
Leah B. Guidry  
Jeffrey D. Kahn  
Rachel Nosowsky  
Eric W. Sitarchuk  
• What are the considerations for compliance programs in AMCs and Universities? What matters to the government, what matters to the faculty and university leadership, what matters in the health care environment?  
• The reporting relationships, areas of responsibility and roles for those responsibilities within legal and compliance; who manages whom and when? How do legal ethics and issues of professional responsibility affect decision-making? |
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<td>Frederick G. Savage</td>
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<td>• Current status of the act and the most recent revisions</td>
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<td>• Initiatives and responses at academic medical centers</td>
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<td>• Related changes in institutional disclosure processes</td>
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<td>• Impact on relationship between manufacturers and academic medical centers</td>
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<td>• The scorecard for all participants: How did we do?</td>
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<td>- CMS</td>
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<td>- Physicians</td>
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<td>- Teaching hospitals</td>
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<td>- AMCs generally</td>
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<td>• Goals of the Open Payments—and were they achieved?</td>
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<td>Almeta E. Cooper</td>
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<td>Hope S. Foster</td>
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<td>• “Immediate Jeopardy” for mistakes in proficiency testing</td>
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<td>• Proposed FDA regulation of laboratory developed tests (In Vitro Testing)</td>
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<td>• Differences in regulations of waived and non waived testing</td>
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<td>• Apply the IRS “unique circumstances” test to laboratory revenue</td>
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<td>• Regulation of hospital clinical laboratories</td>
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<td>Sandra A. Laws</td>
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<td>Andrew D. Ruskin</td>
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<td>• Whether, and how, a community hospital can obtain Medicare reimbursement for training residents</td>
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<td>• Working through issues relating to data disclosed under the Sunshine Act</td>
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<td>• Medicare readmissions and quality data payment penalty exposure</td>
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<td>• Potential risks and benefits of different levels of integration, ranging from a loose affiliation to making one hospital “provider-based” to the other</td>
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<td>• Pre-transaction testing, and post-transaction reinforcing, the robustness of the community hospital compliance plan</td>
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|              | Calling all Life Members! We are hosting a group for dinner together at an area restaurant. Dinner will be on your own dime, but the time spent with your colleagues will be priceless.
Program Agenda

Thursday, January 22, 2015 (continued)

7:30 pm
Hospitals and Health Systems Practice Group’s Public Health Systems and Fair Market Value Affinity Groups and Teaching Hospitals and Academic Medical Centers Practice Group’s Children’s Hospital Affinity Group Networking Dinner
(limited space; RSVP on the registration form on page 15)
Join your colleagues from the sponsoring Affinity Groups for dinner. Dinner will be on your own dime; the networking opportunity will be priceless.

8:00-9:00 am
CONCURRENT SESSIONS
J. Masters Session–Legal Ethics: Advanced Problems in Representing Complex Clients in a Highly Regulated Industry (not repeated)
(space is limited; pre-register on the registration form on page 15)
William W. Horton
Jeff Sconyers
In a discussion format for experienced lawyers representing academic medical centers and teaching hospitals, this session will use a hypothetical scenario to explore complicated legal representation issues. The scenario will present issues and questions in these areas among others:
• Dealing with federal or state investigations
• Representing multiple entities within a system
• Squaring legal analysis with compliance obligations
• Investigating faithless leaders and acting on investigation results
• Providing advice when individuals could face criminal charges or exclusion from government payment programs
• Zealous advocacy in the face of opponents with the potential to impose a corporate “death penalty,” and similar conundra

K. “Big Data” Breaches
Kristen B. Rosati
Most Teaching Hospitals and Academic Medical Centers are creating data warehouses and other “big data” resources to utilize for research, quality improvement activities and other business analytics. Recent data breaches have shown that the health care industry is at an increasing risk of sophisticated hacking, and TH/AMC data warehouses are a prime target for stealing both proprietary information for business espionage and patient information for identity theft. This session will discuss crucial tasks in managing a big data breach, both before and after the beach occurs:
• Assuring that the organization has done a complete security risk assessment and has implemented the resulting security risk management plan
• Implementing a breach response team and communication plan, and identifying security consulting resources
• Determining federal and state breach reporting obligations
• Preparing the patient notices: identifying affected patients, establishing call center functionality, locating identity theft service providers, and producing/mailing patient notices
CONCURRENT SESSIONS
8:00–9:00 am (continued)

L. Fraud and Abuse Update for AMCs
Lisa M. Ohrin
Robert A. Wade
- Recent cases and settlements (including Halifax and Infirmary Health System)—what do they mean to your AMC/practice plan?
- Recent investigations of AMCs, including those by the RAC Program
- Recent developments regarding the Stark Law, Anti-Kickback Statute, and False Claims Act related to AMCs, including revisions to the Stark Law self-disclosure protocol
- Accountable care organizations, bundled payments, and AMCs’ participation

M. Clinical Research Update—How Will New Developments Impact Your Institution?
Ann T. Hollenbeck
Holley Thames Lutz
- Presidential Commission's Report on incidental and secondary findings
  – The report's ethical basis
  – Context-specific recommendations
- OHRP's draft guidance on research evaluating standards of care
  – What are “standards of care”?
  – What is a “risk of research” and what is a “reasonably foreseeable risk”?

N. Graduate Medical Education: Regulations and Ruminations following the Release of IOM Report (not repeated)
Susan J. Banks
Lori K. Mihalich-Levin
- Basics of GME reimbursement
- Current issues with new programs
- Implications and impact of the July 2014 Institute of Medicine (IOM) Report, “Graduate Medical Education that Meets the Nation’s Health Needs”
- Update on GME changes in the FY 2015 Hospital IPPS rulemaking cycle

O. Tiptoe through the Tulips: How to Structure AMC/Physician Collaborations in the Heady World of Post-Reform Health Care Delivery
Claire F. Miley
Keith T. Stroup
- Gainsharing, once a bête noire, is now at the core of many collaborations.
  What is the regulatory pathway for these types of payments? Will the recently proposed OIG rule be a panacea?
- Co-management agreements: Taking the devil out of the details
- What is the prognosis for equity ownership arrangements? A look at specialty hospitals, realty, and equipment
- Clinically integrated networks (“CINs”) are “the new normal,” and everyone is joining them. But how will they affect physician compensation and the willingness of physicians to collaborate?
- Don’t forget the “blocking and tackling” of physician compensation—legitimate business purpose and fair market value. And consider the aggregate effect of all relationships, e.g., compensation stacking and overlap of duties

C. Big Data, Cloud Computing and the New World Order for Health Care Privacy (repeat)
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<td>AMCs and Life Sciences Investors: Working together to Accelerate Commercialization</td>
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<td>Kristian A. Werling, McDermott Well &amp; Emery LLP. Chicago, IL</td>
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Program Faculty

PLANNING COMMITTEE

Ann T. Hollenbeck  
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Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions

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Philadelphia, PA

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Kansas City, MO

Robert A. Wade
Krieg DeVault LLP
Mishawaka, IN

Andrew A. Ziskind, MD
Managing Director
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<td><strong>O. Tiptoe through the Tulips: How to Structure AMC/Physician Collaborations in the Heady World of Post-Reform Health Care Delivery</strong> &lt;br&gt; Milloy Stroup</td>
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<td><strong>C. Big Data, Cloud Computing and the New World Order for Health Care Privacy</strong> (repeat) &lt;br&gt; Arvin Nahra</td>
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<td>Time</td>
<td>Session</td>
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<tr>
<td>10:30-11:45 am</td>
<td>D. Maintaining Independence Through Interdependence—Alliances between AMCs and Community Hospitals (repeat)</td>
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<td>E. Legal Ethics: Who Owns Compliance in an AMC/University? Professional Responsibility and Organizational Considerations (repeat)</td>
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<td>F. The Current State of Sunshine: Scorecard for the AMCs, Physicians, Teaching Hospitals, Industry, and CMS (repeat)</td>
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<tr>
<td>11:45 am-1:00 pm</td>
<td>Lunch on your own or attend the Life Sciences Practice Group Luncheon (limited attendance; additional fee; pre-registration required; see page 15)</td>
</tr>
<tr>
<td>1:15-2:15 pm</td>
<td>A. Built to Last: Anatomy of a Successful Public-Private Partnership between an AMC and Community Specialty Hospital (repeat)</td>
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<td>K. “Big Data” Breaches (repeat)</td>
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<td>L. Fraud and Abuse Update for AMCs (repeat)</td>
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<td>2:30-3:30 pm</td>
<td>H. Reimbursement and Compliance Due Diligence and Integration Considerations in the 21st Century: What Every AMC Needs to Know when Adding a Community Hospital to the System (repeat)</td>
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<tr>
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<td>M. Clinical Research Update—How Will New Developments Impact Your Institution? (repeat)</td>
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<tr>
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<td>O. Tiptoe through the Tulips: How to Structure AMC/Physician Collaborations in the Heady World of Post-Reform Health Care Delivery (repeat)</td>
</tr>
</tbody>
</table>
Program Information

Dates: January 22-23, 2015
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 9, 2015
$695 For the first AHLA/AAMC/NACUA Member
$620 For each additional Member
$920 Non-Members

Postmarked and paid January 10-18, 2015*
$820 For the first AHLA/AAMC/NACUA Member
$745 For each additional Member
$1045 Non-Members

Printed Course Materials: $45

*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) 833-1100, prompt #2 for special discounted registration fees. Additionally, discounted registration fees are available to any individual who expresses the need for such a discount and certifies financial hardship. If you require financial assistance in order to attend the program, please contact Anne H. Hoover, Vice President of Programs at (202) 833-0780 or ahoover@healthlawyers.org to request assistance.

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. We have applied for 12.25 continuing education credits (including 3.0 ethics credit) based on a 60-minute hour and 14.7 credits (including 3.6 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.

AHLA will be applying for Compliance Certification Board (CCB) 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 $270 single/double occupancy are limited and may sell out prior to January 2, 2015.

Membership
Dues are $200 for those admitted to the Bar/graduated from college within the last four years; $320 for those admitted/graduated between four and seven years ago; and $365 for those admitted/graduated eight or more years ago. Dues are $100 for government employees and full-time academicians; $100 for public interest professionals and $25 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 15, 2015. 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 #6. 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.
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) 833-1100, prompt #2. On-site registrations will be accepted on a space-available basis only.
Name: ___________________________________________  AHA Member ID #: ____________________________
First Name for Badge (if different than above): ______________________________________________________
Title: ________________________________________________________________________________________
Organization: ________________________________________________________________________________
Address: _____________________________________________________________________________________
City: _________________________________________________________________________________________
State: _______  ZIP+ 4: ____________________________
Telephone: (______) ________________________  Fax: (______) ______________________________
E-Mail: _____________________________________________________________________________________
I am a member of:  □ AHA  □ NACUA  □ AAMC
Early Registration Fees (faxed/postmarked and paid on or before January 9, 2015):
• AHA/NACUA/AAMC Members: □ $695  Non-Members: □ $920
• Group Members: □ $620 each additional AHA/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 10-18, 2015):
• AHA/NACUA/AAMC Members: □ $820  Non-Members: □ $1045
• Group Members: □ $745 each additional AHA/NACUA/AAMC member registering from same organization at same time on the same check or credit card payment
Discounts
• In-House Counsel/Solo Practitioner  □ $100 off applicable rate
• Government/Academician/Public Interest Attorney:
  □ $495 AHA/NACUA/AAMC Members  □ $570 Non-Members
I will require:  □ audio  □ visual  □ mobility  □ other assistance: __________________________________________
I would like to attend:  □ Life Members Networking Dinner (Thursday, January 22, 7:00 pm)
□ Affinity Group Networking Dinner (Thursday, January 22, 7:30 pm)
□ Women’s Networking Breakfast (Friday, January 23, 7:00 am)
□ Master’s Session-Legal Ethics (Friday, January 23, 8:00 am)

PAYMENT INFORMATION
Please fill in applicable amount: (Sorry! Registrations cannot be processed unless accompanied by payment.)
$________________________  Registration Fee
$________________________  TH/AMC and HIT Practice Group Luncheon ($35 for members of the TH/AMC or HIT PG/$45 for non-members of the TH/AMC and HIT PG; Thursday, January 22, 2015)
$________________________  Life Sciences Practice Group Luncheon ($35 for members of the LS PG/ $45 for non-members of the LS PG, Friday, January 23, 2015)
$________________________  Printed Course Materials ($45)
$________________________  Spouse/Guest Fee ($30); Spouse/Guest Name ___________________________
$________________________  Membership Dues (Date admitted to the bar/graduated: □ □ □ □ □ □ □ □ □ □ □ □)
$________________________  Join the Practice Group (join the PG and pay the member rate for the Luncheon)
□ TH/AMC ($50)  □ HIT ($50)  □ LS ($50)
$________________________  Total Enclosed

☐ Check enclosed (Make checks payable to American Health Lawyers Association)
Bill my credit card:  □  □  □  □  □  □  □  □  □  □  □  □
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, AHA 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 15, 2015.
Fed ID No. 23-7333380
Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions

January 22-23, 2015

Ritz-Carlton Hotel
Washington, DC

Register by January 5 and save! For updates and to register, go to www.healthlawyers.org/programs