Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions

Program Planning Committee
Ann N. James, Program Co-Chair
Heather H. Pierce, Program Co-Chair
Jeffrey D. Kahn
Kristen B. Rosati
Stephen Sencer

Program 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

Program Sponsor

Exhibitors
❯❯ Ntracts LLC
❯❯ PYA

Hotel Information
Baltimore Marriott Waterfront Hotel
700 Aliceanna Street
Baltimore, MD 21202
Phone: (410) 385-3000

Hotel accommodations are not included in the registration fee. Call the Baltimore Marriott Waterfront Hotel at (410) 385-3000 and indicate that you are attending the AHLA program. Rooms at the group rate of $229 single/double occupancy are limited and may sell out prior to the February 15, 2017 cut-off.

Registration Fees:
Postmarked and paid on or before February 15, 2017
$725 first AHLA/NACUA/AAMC Members
$650 each additional AHLA/NACUA/AAMC Members
$975 Non-Members

Postmarked and paid between February 16-March 2, 2017*
$850 first AHLA/NACUA/AAMC Members
$775 each additional AHLA/NACUA/AAMC Members
$1,100 Non-Members

* Fees increase $100 after this date

Discounts
$100 off full applicable rate for In-House Counsel and Solo Practitioner
$550 AHLA Government/Academician/Public Interest Professional Members
$650 Government/Academician/Public Interest Professional Non-Members

Practice Group Luncheon(s):
$55 Members of the sponsoring Practice Group(s)
$60 Non-Members of the sponsoring Practice Group(s)

For the most up-to-date information and to register, visit our website at www.healthlawyers.org/programs
THURSDAY, MARCH 9, 2017
7:00 am-5:30 pm

Registration and Information

GENERAL SESSION
8:00-8:15
Welcome and Introduction
Eric Zimmerman, AHLA President-Elect
Ann N. James, Program Co-Chair
Heather H. Pierce, Program Co-Chair

8:15-9:15 am
Looking Back: The Year in Review
Elizabeth B. Carder-Thompson
It has been another roller coaster year for health care law developments affecting teaching hospitals and AMCs: Reimbursement upheavals, unprecedented fraud and abuse enforcement, HIPAA high jinx, and more. This fast paced session will provide an overview of recent events, and introduce multiple topics to be addressed in later focused program sessions during the conference:
❯❯ Massive regulatory developments: Overpayments, Stark, MACRA, CMS innovation model
❯❯ New research funding under 21st Century Cures
❯❯ $1.45 million punitive damages upheld against hospital for EMTALA violation
❯❯ Ransomware attacks against hospitals—the new HIPAA violation?
❯❯ Sweeping take downs by the Medicare strikeforce
❯❯ Record-breaking numbers of false claims act recoveries
❯❯ The Yates memo on individual culpability in action
❯❯ What to expect from the Trump administration on health care “reform”

9:15-10:15 am
Looking Forward: What’s Ahead for the Academic Medical Center?
Karen S. Fisher
❯❯ Affordable Care Act
❯❯ Medicare and Medicaid
❯❯ Funding and regulation of Graduate Medical Education
❯❯ Funding and regulation of research

10:15-10:30 am
Coffee Break

10:30 am-12:00 noon
Big Issues in Big Data: Doing Research in Large Networks
Gelvina R. Stevenson (Moderator)
Nadine Peters
Richard Platt
Amy J. Sokol

12:15-1:30 pm
Lunch on your own or attend the Academic Medical Centers and Teaching Hospitals Practice Group Luncheon, sponsored by PYA
Title: Emerging Issues in the Area of FDA Regulation
Theodore Ruger, Dean and Bernard G. Segal Professor of Law
University of Pennsylvania Law School, Philadelphia, PA
❯❯ Emerging issues in the area of FDA regulation
❯❯ What may be in store for FDA under the new administration
❯❯ What the impact may be on academic medical centers
This event is not included in the program registration. Limited attendance; additional fee; pre-registration required.

CONCURRENT SESSIONS
1:45-2:45 pm
A. Strategic Alliances with Industry (not repeated)
Maureen Japha
Gary D. Wimsett
❯❯ How institutions can structure ethical partnerships with industry without compromising mission-based strategies and what are the key elements of successful arrangements
❯❯ How regulations and institutional policies related to conflicts of interest help to protect institutions and guide investigators, and when these policies might be seen as barriers to beneficial partnerships
❯❯ What legal issues are considered for external funders, whether from industry or venture philanthropy, obstacles to working with academic institutions and what mechanisms or activities have been suggested or discussed to address these concerns
B. Fraud and Abuse Update for AMCs

Robert A. Wade
Lisa Ohrin Wilson

- Recent court rulings and settlements—what do they mean to your AMC/practice plan?
- Investigations of AMCs (and others), including those by the RAC Program
- Developments regarding the Stark Law, Anti-Kickback Statute, and False Claims Act related to AMCs, including revisions to the Stark Law self-disclosure protocol and the AKS final safe harbors
- Accountable care organizations, bundled payments, and AMCs

C. Legal Risks of Conducting Clinical Studies: An Academic Site Perspective

Mont Brownlee
Karen A. Mullin

- The two different and distinct categories of risk:
  - Risk arising from the performance of the clinical study
  - Risks arising from the use of clinical study data and results
- Risks arising from the performance of a clinical study, including:
  - Study recruitment and enrollment
  - Informed consent process
  - Adverse events and study subject injury
  - Compliance with contractual and regulatory requirements
- Risks arising from the use of clinical study data and results, including:
  - Sponsor’s use of study data and results
  - Site’s and/or investigator’s use of study data and results
  - Confidentiality violations
  - Intellectual property disputes
  - Data breaches involving PHI and cyber security
- Strategies adopted by academic medical sites to effectively manage legal risks of conducting clinical studies

3:00-4:15 pm Extended Sessions

D. Changes to the Regulatory Environment for Research (not repeated)

Kate Gallin Heffernan
Laura Odwazny

- The changes to the Federal regulations governing research with human subjects, known as the Common Rule
- How stakeholder input and public comment on the Notice of Proposed Rulemaking influenced the content of the final rule
- How the regulatory environment for research may change as a result of the requirements set forth in the 21st Century Cures Act and how the revised Common Rule may intersect with the Act’s regulatory mandates

E. Data Sharing for Clinical Integration and Other “Big Data” Initiatives

Kristen B. Rosati
Rachel Nosowsky

Academic medical centers and teaching hospitals are engaging in a variety of different, sophisticated data sharing arrangements, from clinical integration initiatives with community hospitals and physician groups, to complicated care management arrangements with large employer group health plans, to shared data resources for research, to spin-outs of AMC/TH resources to for-profit partners. This session will address:

- Legal parameters around data sharing initiatives
  - Federal and state privacy laws
  - Common rule
  - Antitrust
  - Stark and Anti-Kickback
  - Nonprofit tax-exemption
- Data governance: Setting rules around who can access what data, when, and for what purpose
- Contracting in data sharing initiatives: Breach reporting, risk allocation, limitation of liability

F. Shifting Risks: The New Frontiers of Health Care Payment

Constance L. Akridge
Matthew T. Milone
Susan M. Pitz

- Evolution of payment models for hospitals and medical centers including bundled payments and MACRA
- Concerns and solutions in incorporating bundled payments in light of existing regulations, requirements, and academic mission
- Changing nature of health insurance and its impact on relationship between providers and patients, including issues related to taking provider risk
- Effect of evolving network adequacy standards on academic medical centers including: Revised NAIC model act and CMS network adequacy standards
- Challenges facing academic medical centers and medical school practice plans participating in narrow/tiered networks and high deductible plans
- How payment models impact program support for academic missions

4:30-5:30 pm

G. Our Devices, Ourselves: The Use of Mobile Technologies in Health Care Delivery and Biomedical Research (not repeated)

Ann N. James
Bernadette M. Broccolo

The use of mobile technologies to engage virtually with patients and research subjects is rapidly accelerating, particularly among younger generations of providers,
other health care workers and consumers who see the use of mobile devices through the Internet of Things as an extension of themselves. This session will address both the valuable opportunities the use of mobile technologies presents and the associated legal and regulatory challenges, including:

❯ Universe of consumer-facing and non-consumer facing devices, “apps,” activities, and relationships powered through the Internet of Things Ecosystem
❯ AMC strategies for integrating such mobile technologies into their health care delivery and research activities
❯ Secondary use of patient information obtained through mobile devices to fuel “Big Data”, predictive modeling, clinical decision support, and further development of mobile technology solutions
❯ Changing role of patient in his or her care management and the new dynamics in the provider-patient relationship
❯ Patient safety and medical malpractice issues arising from misuse of and inappropriate reliance on mobile technology and solutions in care management and medical decision making
❯ Emerging privacy and security challenges
❯ Exposure to unanticipated state regulation of telehealth activities and associated reimbursement implications
❯ Evolving strategies for managing the challenges and risks through policies and procedures, patient notice and consent practices, contracting strategies, and other means

H. Legal Ethics: The Impossible Dream? Seeking to Maintain Attorney-Client Privilege in an Age of Internal Investigations, Self-Disclosures, Advice of Counsel, and the Yates Memorandum

Kathryn H. Sasser
Richard W. Westling

❯ Recent developments on attorney-client privilege and work product doctrine in the context of health care investigations and enforcement
❯ Advice of counsel defense and its impact on the ability to protect attorney-client privilege
❯ Subject matter waivers and limited waivers: Are they possible?
❯ Particular challenges to the attorney-client privilege in the in-house setting
❯ Best practices on how to protect and assert privilege and work product protections

J. Incidental Findings in Genomic Research: Ethics, Law, and Practicality

Ann T. Hollenbeck
Katherine B. Steuer

❯ Evaluate the issues that should be addressed by IRBs and institutions conducting human genomic research in order to:
– Develop and implement appropriate policies for managing incidental or secondary findings
– Plan to address issues that may arise in returning genomic results

❯ Become prepared to:
– Consider what is an incidental or secondary finding in genomic research
– Understand the clinical “actionability” debate
– Make decisions about previously stored tissue samples
– Consider Non-CLIA results
– Evaluate the timing and method of disclosure
– Consider the ethics of genomic testing and return of results in pediatrics

5:30-6:30 pm

Networking and Diversity+Inclusion Reception, hosted by AHLA’s Diversity+Inclusion Council, sponsored by PYA

Join AHLA for a combined Welcome Reception and Diversity+Inclusion Reception. Learn more about AHLA’s diversity and inclusion initiatives. Network with AHLA leaders and your fellow colleagues. This event is included in the program registration. Attendees, faculty, and registered spouses and guests are welcome.

FRIDAY, MARCH 10, 2017

7:00 am-4:45 pm

Registration and Information

7:00-8:00 am

Continental Breakfast, sponsored by PYA

This event is included in the program registration. Attendees, faculty, and registered spouses and guests welcome.

CONCURRENT SESSIONS

8:00-9:00 am

K. Designing a Standard Resident Rotation Agreement (Interactive)

(not repeated)

Luke W. Cleland
Frank Trinity

❯ The Association of American Medical Colleges is developing a standard resident rotation agreement to help end the “battle of the forms” among medical residency programs. We need your input!
❯ According to a recent AAMC survey of Designated Institutional Officials (130 respondents), nearly one-half reported a medical resident’s rotation being delayed or even cancelled due to wrangling over terms of agreements, when the legal risk of such arrangements is relatively low
Based on the common sticking points identified in the survey—such as indemnification, insurance, financial issues, background checks, state immunity, governing law, and licensure—we believe that a standard approach is feasible and will save time for residency program administrators and their counsel.

The AAMC is undertaking a project similar to one that resulted in the LCME-endorsed AAMC Uniform Clinical Training Affiliation Agreement (for medical student rotations), adopted by more than 100 institutions to date. That project benefited from a session at the AHLA Academic Medical Center program in DC in 2013, as we gained good feedback and promoted awareness of the project before the Agreement was launched. The 2013 AHLA session also surfaced individual practitioners who volunteered to serve as informal advisors as the project moved to completion.

Follow a similar playbook for residency programs, including seeking input from those experienced in managing these rotations, in consultation with the ACGME and others with a stake in this important stage of graduate medical education.

L. Responding to an OCR Breach Investigation
Susan Stayn (Moderator)
Patrice M. Le Melle
Barbara Holland

How should entities respond to an OCR HIPAA breach investigation?
How does OCR evaluate responses; what tools, protocols, or consultants does it use; and what timing should be expected?
What factors influence OCR’s decision about whether to close an investigation, request corrective action, or pursue a settlement or civil monetary penalties?
What happens during an OCR settlement process?

M. What Every AMC Needs to Know about the 340B Program
Andrew D. Ruskin

340B Program fundamentals
Strategic considerations in striking the optimal balance between GPO and 340B Program purchasing
Determining the limits of who qualifies as a “patient” eligible for 340B drugs for individuals treated at faculty practice plan clinics or at affiliated non-340B hospitals
HRSA rules on “child sites,” as applied to AMC provider-based clinics
Potential future litigation and legislation affecting the 340B Program

10:30-11:45 am Extended Sessions

Q. Dividing to Thrive: How One Great Institution Became Two to Assure Future Success (not repeated)
Audrey J. Anderson
Torrey J. McClary
Michael J. Regier

On April 29, 2016, in one of the most widely-watched transactions in academic medicine and in the health care industry, Vanderbilt University conveyed its health care business and operations into a separate, nonprofit corporation known as Vanderbilt University Medical Center. As a result, the University and Medical Center are now distinct legal entities but with common mission objectives and many shared activities. In this session, the general counsels of the two now-separate organizations, along with outside counsel who represented the University in the transaction, will discuss:
 Strategic reasons behind the decision to separate, and the process used by the University to reach that decision

Financial, regulatory, and other challenges which may lead other universities to consider restructuring their relationships with their affiliated medical centers

“Early returns” on implementing the separation, including the nature of the on-going academic and clinical affiliation between the parties, and how what was once “business as usual” has been affected by the transaction

E. Data Sharing for Clinical Integration and Other “Big Data” Initiatives (repeat)

F. Shifting Risks: The New Frontiers of Health Care Payment (repeat)

11:45 am-1:00 pm

Lunch on your own or attend the Life Sciences Practice Group Luncheon

Title: Research in an Age of Digital Data: Perspectives in Policy-Making

Lucia C. Savage, Former Chief Privacy Officer, Office of the National Coordinator for Health IT, US Department of Health and Human Services, Washington, DC

Based on her experience as Chief Privacy Officer at the Health and Human Services Office for the National Coordinator for Health IT from 2014 to 2017, Ms. Savage will discuss some of the novel and complex ethical, privacy, and security issues that the federal government grappled with bringing visions for a learning health system, the Precision Medicine Initiative, Patient-Centered Outcomes Research, and the Cancer Moonshot to life. Specific material will cover:

❯❯ How concepts first articulated in the Belmont Report manifest in a digital world, including the perspectives of health data innovators, consumers, and researchers
❯❯ New issues due to genomic sequencing
❯❯ New issues due to a culturally diverse population of research participants
❯❯ Maintaining privacy in an age of ever-accelerating ability to combine and filter digital data sets
❯❯ New perspectives of the activated engaged patient, including return of results, self-confidence, and justified impatience, and patient-contributed data from trackers, apps, and the “quantified self” movement
❯❯ Security, including: cyber security attacks; marquee targets; federated credentials for multi-site research; and whether we regulate what people do with their health data

This event is not included in the program registration. Attendees and faculty welcome. There is an additional fee; pre-registration is required; space is limited.

CONCURRENT SESSIONS

1:15-2:15 pm

R. Making Sense of MACRA in the AMC Setting: Adapting to the New Quality Payment Program (not repeated)
   Glenn P. Prives
   Jessica E. Stack
   Kristen McDermott Woodrum

Practical, regulatory and fair market value considerations for AMCs navigating MACRA and value-based physician compensation including:

❯❯ Balancing many goals: Research and teaching, clinical, and now quality
❯❯ Selecting the pathway and performance goals, recognizing differences in an AMC delivery system
❯❯ Evaluating and restructuring compensation models
❯❯ Market trends and challenges of using quality metrics for hospital compensation of physicians. While HHS is aggressively pushing reimbursement along the value-based continuum, providers still have footing and commercial contracting arrangements in the fee-for-service world
❯❯ Practical challenges and legal barriers in implementing quality-based compensation and alignment models for AMCs
❯❯ Roles and responsibilities of hospital compensation committee

H. Legal Ethics: The Impossible Dream? Seeking to Maintain Attorney-Client Privilege in an Age of Internal Investigations, Self-Disclosures, Advice of Counsel, and the Yates Memorandum (repeat)

J. Incidental Findings in Genomic Research: Ethics, Law, and Practicality (repeat)

2:30-3:30 pm

B. Fraud and Abuse Update for AMCs (repeat)

C. Legal Risks of Conducting Clinical Studies: An Academic Site Perspective (repeat)

P. Ownership of Invention–Tech Transfer and Royalties Issues (repeat)

3:45-4:45 pm

L. Responding to an OCR Breach Investigation (repeat)

M. What Every AMC Needs to Know about the 340B Program (repeat)

O. It Takes A Village: AMC Outreach to Community Physicians in the Age of Value-Based Reimbursement (repeat)

Adjournment
# Program at a Glance

**THURSDAY, MARCH 9, 2017**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 am-5:30 pm</td>
<td>Registration and Information</td>
</tr>
<tr>
<td>8:00-8:15 am</td>
<td>General Session</td>
</tr>
<tr>
<td></td>
<td>Welcome and Introduction</td>
</tr>
<tr>
<td></td>
<td>Zimmerman, James, Pierce</td>
</tr>
<tr>
<td>8:15-9:15 am</td>
<td>General Session</td>
</tr>
<tr>
<td></td>
<td>Looking Back: The Year in Review</td>
</tr>
<tr>
<td></td>
<td>Carder-Thompson</td>
</tr>
<tr>
<td>9:15-10:15 am</td>
<td>General Session</td>
</tr>
<tr>
<td></td>
<td>Looking Forward: What’s Ahead for the Academic Medical Center?</td>
</tr>
<tr>
<td></td>
<td>Fisher</td>
</tr>
<tr>
<td>10:15-10:30 am</td>
<td>Break</td>
</tr>
<tr>
<td>10:30 am-12:00 noon</td>
<td>General Session</td>
</tr>
<tr>
<td></td>
<td>Big Issues in Big Data: Doing Research in Large Networks</td>
</tr>
<tr>
<td></td>
<td>Stevenson (Moderator), Peters, Platt, Sokol</td>
</tr>
<tr>
<td>12:15-1:30 pm</td>
<td>Lunch on your own or attend the Academic Medical Centers and Teaching Hospitals Practice Group Luncheon, <em>sponsored by PYA</em></td>
</tr>
<tr>
<td></td>
<td>(This event is not included in the program registration. Limited attendance; additional fee; pre-registration required)</td>
</tr>
<tr>
<td>1:45-2:45 pm</td>
<td>Concurrent Sessions</td>
</tr>
<tr>
<td>A. Strategic Alliances with Industry</td>
<td>(not repeated)</td>
</tr>
<tr>
<td></td>
<td>Japha</td>
</tr>
<tr>
<td></td>
<td>Wimsett</td>
</tr>
<tr>
<td>B. Fraud and Abuse Update for AMCs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wade</td>
</tr>
<tr>
<td></td>
<td>Wilson</td>
</tr>
<tr>
<td>C. Legal Risks of Conducting Clinical Studies: An Academic Site Perspective</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Brownlee</td>
</tr>
<tr>
<td></td>
<td>Mullin</td>
</tr>
</tbody>
</table>
### THURSDAY, MARCH 9, 2017 (Continued)

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenters</th>
</tr>
</thead>
<tbody>
<tr>
<td>3:00-4:15 pm</td>
<td>Extended Sessions</td>
<td></td>
</tr>
<tr>
<td>D. Changes to the Regulatory Environment for Research (not repeated)</td>
<td>Heffernan</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Odwazny</td>
</tr>
<tr>
<td>E. Data Sharing for Clinical Integration and Other “Big Data” Initiatives</td>
<td>Nosowsky</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rosati</td>
</tr>
<tr>
<td>F. Shifting Risks: The New Frontiers of Health Care Payment</td>
<td>Akridge</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Milone</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pitz</td>
</tr>
<tr>
<td>4:30-5:30 pm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>G. Our Devices, Ourselves: The Use of Mobile Technologies in Health Care Delivery and Biomedical Research (not repeated)</td>
<td>Broccolo</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>James</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Westling</td>
</tr>
<tr>
<td>J. Incidental Findings in Genomic Research: Ethics, Law, and Practicality</td>
<td>Hollenbeck</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Steuer</td>
</tr>
<tr>
<td>5:30-6:30 pm</td>
<td>Networking and Diversity+Inclusion Reception, hosted by AHLA’s Diversity+Inclusion Council, sponsored by PYA (This event is included in the program registration. Attendees, faculty, and registered spouses and guests are welcome)</td>
<td></td>
</tr>
</tbody>
</table>

### FRIDAY, MARCH 10, 2017

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenters</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 am-4:45 pm</td>
<td>Registration and Information</td>
<td></td>
</tr>
<tr>
<td>7:00-8:00 am</td>
<td>Continental Breakfast, sponsored by PYA (This event is included in the program registration. Attendees, faculty, and registered spouses and guests welcome)</td>
<td></td>
</tr>
<tr>
<td>8:00-9:00 am</td>
<td>Concurrent Sessions</td>
<td></td>
</tr>
<tr>
<td>K. Designing a Standard Resident Rotation Agreement (Interactive) (not repeated)</td>
<td>Cleland</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Trinity</td>
</tr>
<tr>
<td>L. Responding to an OCR Breach Investigation</td>
<td>Stayn (Moderator)</td>
<td>Le Melle</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Holland</td>
</tr>
<tr>
<td>M. What Every AMC Needs to Know about the 340B Program</td>
<td>Ruskin</td>
<td></td>
</tr>
</tbody>
</table>
### FRIDAY, MARCH 10, 2017 (Continued)

#### 9:15-10:15 am

| N. AMC Agreements—Legal Ethics in Negotiations  
(not repeated) | O. It Takes A Village: AMC Outreach to Community Physicians in the Age of Value-Based Reimbursement | P. Ownership of Invention–Tech Transfer and Royalties Issues |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Buck Spahn</td>
<td>Bulliet Milestone</td>
<td>Sencer Sherer</td>
</tr>
</tbody>
</table>

#### 10:30-11:45 am Extended Sessions

| Q. Dividing to Thrive: How One Great Institution Became Two to Assure Future Success  
(not repeated) | E. Data Sharing for Clinical Integration and Other “Big Data” Initiatives  
(repeat) | F. Shifting Risks: The New Frontiers of Health Care Payment  
(repeat) |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Anderson McClary Regier</td>
<td>Nosowsky Rosati</td>
<td>Akridge Milone Pitz</td>
</tr>
</tbody>
</table>

#### 11:45 am-1:00 pm

**Lunch on your own or attend the Life Sciences Practice Group Luncheon**  
(This event is not included in the program registration. Attendees and faculty welcome. There is an additional fee; pre-registration is required; space is limited.)

#### 1:15-2:15 pm Concurrent Sessions

| R. Making Sense of MACRA in the AMC Setting: Adapting to the New Quality Payment Program  
(not repeated) | H. Legal Ethics: The Impossible Dream? Seeking to Maintain Attorney-Client Privilege in an Age of Internal Investigations, Self-Disclosures, Advice of Counsel, and the Yates Memorandum  
(repeat) | J. Incidental Findings in Genomic Research: Ethics, Law, and Practicality  
(repeat) |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prives Stack Woodrum</td>
<td>Sasser Westling</td>
<td>Hollenbeck Steuer</td>
</tr>
</tbody>
</table>

#### 2:30-3:30 pm

| B. Fraud and Abuse Update for AMCs  
(repeat) | C. Legal Risks of Conducting Clinical Studies: An Academic Site Perspective  
(repeat) | P. Ownership of Invention–Tech Transfer and Royalties Issues  
(repeat) |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Wade Wilson</td>
<td>Brownlee Mullin</td>
<td>Sencer Sherer</td>
</tr>
</tbody>
</table>
3:45-4:45 pm

L. Responding to an OCR Breach Investigation
   (repeat)
   Stayn (Moderator)
   Le Melle
   Holland

M. What Every AMC Needs to Know about the 340B Program
   (repeat)
   Ruskin

O. It Takes A Village: AMC Outreach to Community Physicians in the Age of Value-Based Reimbursement
   (repeat)
   Bulleit
   Milestone

Live Tweet the Program Using #AHLA17

Will you be in Baltimore for the Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions? We encourage you to live tweet @healthlawyers so that attendees can learn from more than one session at once, and so that members unable to attend still feel plugged in.
Faculty

Planning Committee

Ann N. James, Program Co-Chair
Senior University Counsel
Office of the General Counsel
Stanford University
Stanford, CA

Heather H. Pierce, Program Co-Chair
Senior Director, Science Policy, and Regulatory Counsel
Association of American Medical Colleges
Washington, DC

Jeffrey D. Kahn
Executive Vice President and General Counsel
The Children’s Hospital of Philadelphia
Philadelphia, PA

Kristen B. Rosati
Coppersmith Brockelman PLC
Phoenix, AZ

Stephen Sencer
Senior Vice President and General Counsel
Emory University
Atlanta, GA

Constance L. Akridge
Holland & Hart LLP
Las Vegas, NV

Audrey J. Anderson
Vice-Chancellor
Vanderbilt University
Nashville, TN

Bernadette M. Broccolo
McDermott Will & Emery LLP
Chicago, IL

Mont Brownlee
Associate Director, Contracting Office of Research Administration
Johns Hopkins University
Baltimore, MD

Charles R. Buck
McDermott Will & Emery LLP
Boston, MA

Thomas N. Bulleit
Ropes & Gray LLP
Washington, DC

Elizabeth B. Carder-Thompson
Reed Smith LLP
Washington, DC

Luke W. Cleland
Associate General Counsel
University Hospitals
Shaker Heights, OH

Karen S. Fisher
Senior Director and Senior Policy Counsel, Healthcare Affairs
Association of American Medical Colleges
Washington, DC

Kate Gallin Heffernan
Verrill Dana
Boston, MA

Barbara Holland
Regional Manager
Office for Civil Rights
US Department of Health and Human Services
Philadelphia, PA

Ann T. Hollenbeck
Honigman Miller Schwartz and Cohn LLP
Detroit, MI

Maureen Japha
Director, Regulatory Policy; Legal Counsel, Milken Institute FasterCures
Washington, DC

Torrey J. McClary
Hogan Lovells LLP
Los Angeles, CA

Patrice M. Le Melle
Columbia University
New York, NY

Joseph Milestone
Associate General Counsel
Rutgers University
New Brunswick, NJ

Matthew T. Milone
Senior Associate Dean, Legal Affairs
University of Nevada School of Medicine
Reno, NV

Karen A. Mullin
Chief General Counsel/Director of Technology Development
The Forsyth Institute
Cambridge, MA

Rachel Nosowsky
Deputy General Counsel
University of California
Oakland, CA

Laura Odwazny
Senior Attorney
Public Health Division, Office of the General Counsel, US Department of Health and Human Services
Rockville, MD

Nadine Peters
Associate General Counsel
Office of the General Counsel
Patient-Centered Outcomes Research Institute (PCORI)
Washington, DC
Susan M. Pitz
General Counsel
University Medical Center of Southern Nevada
Las Vegas, NV

Richard Platt
Professor and Chair of the Department of Population Medicine
Harvard Pilgrim Health Care Institute
Boston, MA

Glenn P. Prives
McElroy Deutsch Mulvaney & Carpenter LLP
Morristown, NJ

Michael J. Regier
General Counsel and Secretary
Vanderbilt University Medical Center
Nashville, TN

Andrew D. Ruskin
Morgan Lewis & Bockius LLP
Washington, DC

Kathryn H. Sasser
Vice President, Associate General Counsel, Litigation
LifePoint Health
Brentwood, TN

Todd Sherer
Associate Vice President for Research, Executive Director
Emory University
Atlanta, GA

Amy J. Sokol
Associate General Counsel and Risk Manager
University of Kansas Medical Center
Kansas City, KS

Thomas E. Spahn
McGuireWoods LLP
McLean, VA

Jessica E. Stack
Veralon Partners
New York, NY

Frank Trinity
Chief Legal Officer
Association of American Medical Colleges
Washington, DC

Robert A. Wade
Barnes & Thornburg, LLP
South Bend, IN

Richard W. Westling
Waller Lansden Dortch & Davis, LLP
Nashville, TN

Lisa Ohrin Wilson
Senior Technical Advisor
Centers for Medicare and Medicaid Services
Baltimore, MD

Gary D. Wimsett
Director, Conflict of Interest Program
University of Florida
Gainesville, FL

Kristen McDermott Woodrum
BakerHostetler
Atlanta, GA

Frank Trinity
Chief Legal Officer
Association of American Medical Colleges
Washington, DC

Robert A. Wade
Barnes & Thornburg, LLP
South Bend, IN

Richard W. Westling
Waller Lansden Dortch & Davis, LLP
Nashville, TN

Lisa Ohrin Wilson
Senior Technical Advisor
Centers for Medicare and Medicaid Services
Baltimore, MD

Gary D. Wimsett
Director, Conflict of Interest Program
University of Florida
Gainesville, FL

Kristen McDermott Woodrum
BakerHostetler
Atlanta, GA
Continuing Education Credit Information

CLE/MCLE: AHLA will be applying for 13.0 credits (including 2.0 ethics credit) for 60-minute states and approximately 15.6 credits (including 2.4 ethics credit) for 50-minute states.

CPE: AHLA will be applying for 15.0 CPE credits.

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

CCB: AHLA will be applying for 15.6 Compliance Certification Board (CCB) credits.

Participants will be given Continuing Education Request forms at the program. Forms must be completed and returned to AHLA staff to receive credit. The sessions, unless otherwise designated, are intermediate to advance in level. This program is designed to be an update on developments in the area of health law. 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 and terminology associated with health law in order to obtain the full educational benefit of this program.

Membership

Dues are $220 for those admitted to the Bar/graduated from college within the last four years; $340 for those admitted/graduated between four and seven years ago; and $385 for those admitted/graduated eight or more years ago. Dues are $105 for government employees and full-time academicians; $89 for paralegals, $110 for public interest professionals, and $85 for retired professionals. 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 February 27, 2017. 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.

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. Children are welcome to attend these events at no additional charge.

Travel

Association Travel Concepts (ATC) has negotiated discounts with United, Delta, Hertz, and Enterprise Rental Car to bring you special airfares and car rental rates lower than those available to the public. Discounts apply for travel for AHLA 2017 meetings, discounts available 3 days pre/post meeting start/end dates. Restrictions 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
e-mail: reservations@atcmeetings.com
http://www.atcmeetings.com/ahla
ATC is available for reservations from 8:30 am until 8:00 pm Eastern, Monday through Friday.