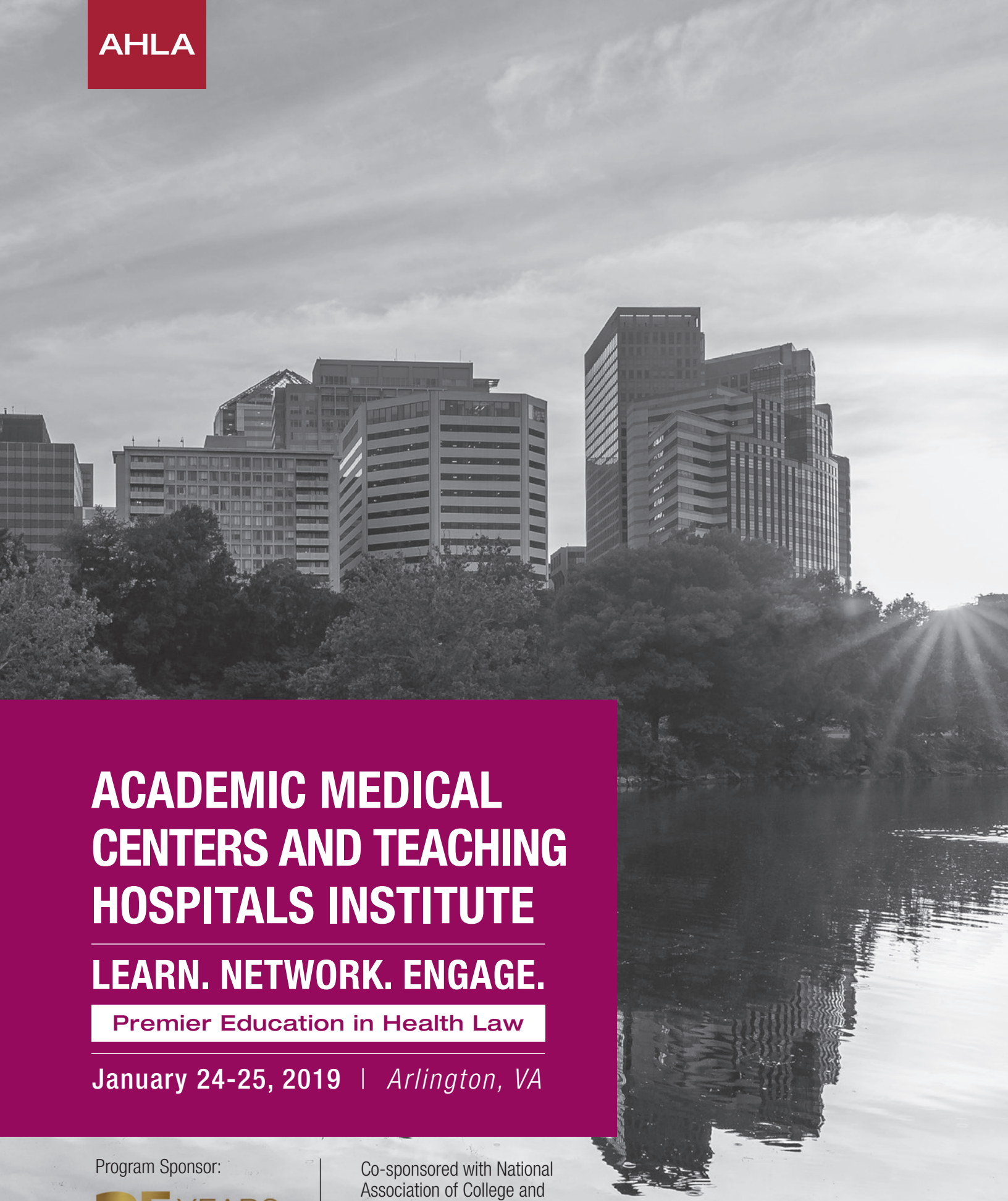
AHLA



ACADEMIC MEDICAL CENTERS AND TEACHING HOSPITALS INSTITUTE

LEARN. NETWORK. ENGAGE.

Premier Education in Health Law

January 24-25, 2019 | *Arlington, VA*

Program Sponsor:

35 YEARS PYA 1983 2018

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

ACADEMIC MEDICAL CENTERS AND TEACHING HOSPITALS INSTITUTE

Planning Committee

Heather H. Pierce, *Program Chair*
Jeffrey D. Kahn
Kristen C. Kim
Kristen B. Rosati
Stephen Sencer

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 and Luncheon Sponsor

35 YEARS PYA 1983 2018

eProgram Sponsor

ECG MANAGEMENT CONSULTANTS

Signage Sponsor

NTRACTS Contracts Without Complications

Registration Fees:

Postmarked and paid on or before January 7, 2019

$775 first AHLA/NACUA/AAMC Member

$700 each additional Member

$1025 Non-Member

Postmarked and paid between January 8-16, 2019*

$900 first AHLA/NACUA/AAMC Member

$825 each additional Member

$1150 Non-Member

* Fees increase $100 after this date

Discounts

(please note: discounts cannot be combined)

$100 off full applicable rate In-House Counsel/ Solo Practitioner

$625 Government/Academician/Public Interest Professional AHLA/NACUA/AAMC Member

$725 Government/Academician/Public Interest Professional Non-Member

$390 One-Day Registration AHLA/NACUA/AAMC Member

$515 One-Day Registration Non-Member

Practice Group Luncheon

$60 Member of sponsoring Practice Group(s)

$70 Non-Member of sponsoring Practice Group(s)

Hotel Information

Crystal Gateway Marriott

1700 Jefferson Davis Hwy
Arlington, VA 22202
(703) 920-3230

Hotel accommodations are not included in the registration fee. Call the Crystal Gateway Marriott at (703) 920-3230 and indicate that you are attending the AHLA program. Rooms at the group rate of $189 single/double occupancy are limited and may sell out prior to the Wednesday, January 2, 2019 cut-off.

Continuing Education Credit Information

CLE/MCLE: AHLA will be applying for 11.75 credits (including 1.0 ethics credit) for 60-minute states and approximately 14.1 credits (including 1.2 ethics credit) for 50-minute states.

CPE: AHLA will be applying for 14.0 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 14.1 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 in level. This program is designed to be an update on developments in the area of academic medical centers and teaching institutions 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 $235 for those admitted to the Bar/ graduated from college within the last four years; $355 for those admitted/graduated between four and seven years ago; and $400 for those admitted/graduated eight or more years ago. Dues are $120 for government employees and full-time academicians; $105 for paralegals, $125 for public interest professionals, and $100 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 by January 14, 2019 and sent to Dorothy Johnson: djohnson@healthlawyers.org. Registration fee, minus the $125 administrative fee, will be refunded approximately 3-4 weeks following the program in the same form of tender as the original payment. Refunds will not be issued for cancellations received after the cancellation date, to include no-shows.

Substitutions will be accepted, in writing to AHLA (djohnson@healthlawyers.org), up to 2 business days prior to the event date on a one time basis. Note, that the registration fee is based on AHLA membership status of the individual who actually attends the program. Non-member substitutes will be charged the fee difference if they are substituting for a member-discounted registration. An administrative fee of $125 will be charged for a substitution request.

Transfer to an upcoming event within one year of equal or higher value is available on a one time basis only, and should be received in writing to AHLA (djohnson@healthlawyers.org.) no later than 2 business days prior to the event. An administrative fee of $125 will be charged for a transfer request.

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. Please sign up on the registration form. (Children are welcome to attend these events at no additional charge.)

Travel

ATC Travel Management (ATC) has negotiated discounts with Delta, Hertz, and Alamo to bring you special airfares and car rental rates lower than those available to the public. Discounts apply for travel for AHLA 2019 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.

ATC TRAVEL MANAGEMENT

1-800-458-9383
email: reservations@atcmeetings.com

ATC is available for reservations from 8:30 am until 8:00 pm Eastern, Monday through Friday.

For the most up-to-date information and to register, visit our website at: **www.healthlawyers.org/programs**

Thursday, January 24, 2019

7:00 am-5:15 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.

General Session

8:00-8:15 am

Welcome and Introduction

Robert R. Niccolini, AHLA President-Elect

Heather H. Pierce, Program Chair

8:15-9:30 am

Building On #MeToo to Enhance the Learning Environment in U.S. Medical Schools

Theresa J. Colecchia (Moderator)
Karen H. Antman
Liza H. Gold

- US Medical schools culture is transitioning from hypercompetitive and hierarchical to team-based collaborative health care. Sexual harassment remains an issue in medical schools in the US and other countries. A third to half of women medical school faculty report at least one episode of sexual harassment. Harassment of medical students remains common.
- Institutional responses include NSF & NIH Reporting requirements for PIs found guilty of sexual harassment, the Impact of National Academies study of sexual harassment in academia and the new U.S. Department of Education's regulations on campus sexual misconduct.

Best practices moving forward:

- Educational programs must ensure that faculty, students and staff recognize sexual misconduct, and that leaders know their reporting requirements and learners have support to report incidents they experience and observe. Medical schools must equip learners, faculty and staff to prevent or escape abuse, and to intervene if they observe a colleague being targeted.
- Institutions should pursue sexual harassment investigations to their completion rather than terminating investigations if the accused faculty member resigns before the investigation has concluded.
- Supervisors who do not promptly investigate complaints are also now being held to a higher standard.
- Decreasing the incidence of sexual harassment (and harassment and discrimination behaviors in general), will improve the learning and working environment of US medical schools.

9:30-10:30 am

Startup Companies and Institutional Opportunities and Risks

Mark Crowell

- Why innovation and commercialization are priorities for AMCs (e.g., the clients of AMC lawyers!)
- How AMC lawyers can get over their fear of flying (ie, don't criticize what you can't understand)
- Balancing the mandates for commercialization and economic development vs. the mandate for conflict of interest management
- Red flags which should cause AMC lawyers to stop, look and ask more
- Financial interests and governing/operational roles of faculty members/founders
- Research misconduct in connection with licensed technology

CONCURRENT SESSIONS

10:45 am-12:00 noon Extended Sessions

A. Year in Review–Research Regulations, Investigations, and Hot Topics *(not repeated)*

Lisa Nichols
Andrew P. Rusczek

This review of the year's hottest topics in research will provide you with an overview and opportunity to discuss what happened in 2018–and how you should be preparing for 2019. Learn about:

- Key concerns from institutions in the week following the implementation deadline for the revised Common Rule
- Government enforcement actions and research misconduct findings that institutions should be watching
- The impact of the CRISPR gene-editing announcement on recombinant DNA research
- How discussions around conflicts of interest in research have taken on new urgency
- New policies, guidance, upcoming initiatives, and 2019 priorities for NIH and other science agencies

B. Physician Comp under the *Qui Tam* Microscope–A Case Study

Jonathan L. Diesenhaus (Moderator)
Jane E. Jordan
Laurie A. Oberembt

Lessons from a multi-year investigation under the False Claims Act, the Stark Law and the Anti-kickback Statute

- Demystifying complex physician comp plans for investigators
- Working with experts and consultants on fair market value and commercial reasonableness
- Monitoring and documenting compliance with contracts and law
- Identifying and analyzing referrals and "resulting" claims

C. Opposites Attract: New Relationships Between AMCs and Managed Care Organizations

Jeffrey C. Baxter
John O. Chesley
Diana Leech

Managed care organizations and AMCs are experimenting with new relationships. These are expressed in a variety of forms, including investment by insurers in joint ventures with AMCs, unusually long-term managed care contracts, and a commitment to leveraging the distinct knowledge resources of the managed care organization and AMC. The session will draw on the experience of internal AMC and managed care organization counsel, and outside counsel transactional AMC practice, to explore:

- Structures
- Motivations
- Challenges of recent collaborations between managed care organizations and AMCs

12:00 noon-1:15 pm

Lunch on your own or attend the Academic Medical Centers and Teaching Hospitals and Life Sciences Practice Groups Luncheon, *sponsored by PYA*

Topic: The Changing Health Care Landscape: Observations from a Reporter on the Hill

Kimberly Leonard
Washington Examiner, Washington, DC

This event is not included in the program registration. Limited attendance; additional fee; pre-registration required. Continuing Education Credits are not available for the luncheon.

CONCURRENT SESSIONS

1:30-2:30 pm

D. Impact of the European Union's General Data Protection Regulation on Research Conducted at U.S. Academic Medical Centers *(not repeated)*

Dina Marty
David Peloquin

The European Union's landmark privacy legislation, the General Data Protection Regulation (GDPR), took effect on May 25, 2018. The law has a broad extra-territorial reach, but determining its application to research conducted at, or supported by, U.S. academic medical centers (AMCs) can be challenging. In this session, the speakers will address several scenarios in which the GDPR affects research conducted at U.S. AMCs and offer practical tips for addressing each fact pattern as well as a general framework for analyzing the impact of the GDPR on other types of research studies. Scenarios reviewed will include the following:

- Serving as a clinical trial site in a multi-site trial sponsored by an EU-based pharmaceutical or medical device company
- Performing services as a vendor for an EU-based pharmaceutical or medical device company
- Serving as a lead site or data coordinating center for a National Institutes of Health-sponsored clinical trial with sites located in the EU
- Collaborating with academic centers in the EU on secondary research involving data sets collected in the EU
- Conducting research in the EU that is "exempt" under the U.S. Common Rule but that involves the collection of personal data
- Engaging a vendor located in the EU to perform services for a research study enrolling participants solely in the U.S.

E. Academic Medical Centers Investing in Innovation

Catherine E. Livingston
Susan Solomon

- Investing in hospital or medical innovation
- Providing equity interests or other compensation to investigators and managers while maintaining tax-exempt status for the AMC
- Anticipating conflicts of interest
- Potential fraud and abuse issues
- Private use of bond-financed facilities

F. Health Equity and Community Benefit; Tax-Exempt Status for Hospitals

Philip M. Alberti
Natasha Davis

- Community benefit legal framework
- The application of community benefit beyond the minimum standards. Nationwide Children's Hospital's national benchmark application of community benefit transformation of a 52 block high crime area in Columbus, Ohio
- National trends re: How academic health centers are allocating community benefit (CB) dollars and implementing community health assessments and interventions (CHNA)
- The potential of CHNA/CB activities to serve as an organizing principle for community-relevant and partnered work across the research, education, and clinical missions of academic medicine

2:45-3:45 pm

G. Marijuana–An Overview of Select Legal Issues *(not repeated)*

Vanessa K. Burrows

- The status of cannabis under federal laws and guidance
- Medical marijuana and potential impacts on licensure
- Medical marijuana use in clinical care and operations
- Policies on patient possession and use of medical marijuana
- Issues with employee consumption of cannabis
- Research on medical uses of cannabis

H. Legal Ethics: The Grey Zone–Ethical Issues in between Compliance and Legal

Dawn R. Crumel
Jennifer Wooten Ierardi
Kim Harvey Looney

- Intersection of compliance and legal in protecting the organization
- Communication and coordination issues when compliance and legal aren't on the same page
- The role of Rules of Professional Conduct in these situations
- Reality of Compliance making independent reports to the board
- Hypothetical situations

I. Recycle, Recycle, Recycle: Key Considerations for Research, Medical Education, and Other Secondary Uses of Data

Jiayan Chen
Leah A. Voigt

With the proliferation of electronic medical records and increasing digitization of health care, enthusiasm over the possibilities of leveraging data for secondary use has reached an all-time high. A historical lack of harmonization in requirements under FDA regulations, the federal research regulations

known as the Common Rule, and HIPAA, however, injected regulatory risk and uncertainty into efforts to repurpose health care data. As regulators work to modernize and align their regimes and provide more clarity and pathways to tap into the promise of big data, it is critical to understand the evolving legal framework and business and compliance imperatives behind the quest for digital health information. This session will cover:

- Evolving areas of convergence and ambiguity across the Common Rule (including the January 2017 final rule), HIPAA, and FDA regulations regarding secondary use of data
- Key changes under the Common Rule final rule regarding secondary use and future research
- Key steps by FDA to facilitate the use of real world data and electronic health records in clinical investigations, and attendant compliance challenges
- How to navigate secondary use in light of concerns regarding privacy in the digital and genomic age
- Planning and contracting strategies that anticipate downstream, secondary purposes, or needs and manage attendant risks

4:00-5:15 pm
Extended Sessions

J. Navigating International Waters–Complying with the Foreign Corrupt Practices Act while Expanding Your Institution's International Presence *(not repeated)*

Christine Genaitis (Moderator)
Alyssa Greenwald
Jennifer M. Ryan

- Brief overview of the FCPA
- Recent FCPA policy developments handed down by the U.S. Department of Justice
- Suggestions for how to implement a robust FCPA compliance program
- Real-world scenarios that implicate the FCPA that medical schools and teaching hospitals face as they seek to grow their international presence.
- Best practices for preventing, mitigating, and remediating issues that implicate the FCPA

B. Physician Comp under the *Qui Tam* Microscope–A Case Study (repeat)

C. Opposites Attract: New Relationships between AMCs and Managed Care Organizations *(repeat)*

5:15-6:15 pm

Networking and Diversity+ Inclusion Reception,
Hosted by AHLA's Diversity+ Inclusion Council, sponsored by PYA

Join us and your colleagues and learn more about AHLA's diversity and inclusion initiatives and network with AHLA leaders and your fellow colleagues. This event is included in the program registration. Attendees, faculty, and registered spouses and guests welcome.

Friday, January 25, 2019

7:00 am-2:45 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.

General Session

8:00-9:00 am

The State of the Academic Medical Center

Keith Horvath

- What is the value of Academic Medicine?
  - o With sicker, more complicated patients, how do outcomes and costs at AMCs compare?
  - o How is value assessed by the Federal government?
- Explore the two major trends impacting Academic Medicine:
  - o The recent spate of mergers and acquisitions, including examples and key considerations
  - o The transition from volume to value as the basis for healthcare payments, and the attendant change in financial risk for AMCs

9:00-10:00 am

Developments in Drug Policy: A look at the 340B Drug Discount Program and Intellectual Property Rights Around Drug Pricing

Jessica Sebeok
Maureen Testoni

- Congressional action in 2018 around the 340B Drug Discount Program
- HHS developments around 340B
- Expectations for the 340B Program in 2019
- Possible congressional actions on drug pricing in the intellectual property context

CONCURRENT SESSIONS

10:15-11:15 am

K. Graduate Medical Education: Hot Topics in Medicare Reimbursement *(not repeated)*

Tim Johnson
Lori K. Mihalich-Levin
David J. Vernon

- Medicare payments for graduate medical education
- Accreditation and funding proposals that attempt to influence residency goals and metrics
- New CMS rules and commentary: Affiliated groups and IRIS reporting
- Medicare rules regarding newly-accredited residency and fellowship programs
- GME funding implications of St. Francis v. Burwell, regarding "predicate facts"

L. Hot Health Information Technology Developments in 2018 *(not repeated)*

Patricia Valarde Burnett
Thomas Ferrante

This session will cover legal issues involved in cutting edge health information technology, including:

- Remote patient monitoring: Regulatory updates, reimbursement opportunities, and contracting for services
- Evolving "non-face-to-face" services and how they differ from traditional "telemedicine" services
- Blockchain technology:
  - What is it and what it can (and cannot) bring to the healthcare industry
  - Key considerations for legal agreements to implement a blockchain technology consortium, including intellectual property ownership rights, data use and management rights, issues triggered by exiting consortia, and compliance issues in creating incentives to participate

M. Don't Put the Car-T before the Horse: Proper Planning for Novel Gene Therapies in an Uncertain Regulatory Environment

Valerie Rinkle
Andrew D. Ruskin

- CAR-T, and why it is unique among drug products
- Program integrity and Medicare billing integrity issues associated with CAR-T clinical trial agreements, including clinical trial budgeting
- The applicable payment systems and why hospitals in some cases may need to furnish these services at a substantial loss, including a discussion of proposed revisions to these payment systems
- Models for health systems to work with manufacturers to reduce a hospital's exposure to payment risk that do not raise program integrity concerns

11:15 am-12:15 pm

Lunch on your own

CONCURRENT SESSIONS

12:30-1:30 pm

N. Developing a Policy on Access to Investigational Drugs: Helping Academic Medical Centers and Teaching Hospitals Respond to "Right to Try" *(not repeated)*

Kate G. Heffernan
Holly Fernandez Lynch

- The origins of "Right to Try"
- The parameters of the federal law
- Comparing the Expanded Access and Right to Try pathways
- Considerations when facilitating access through "Right to Try" (pros and cons for stakeholders)
- Specific implementation challenges such as: Navigating federal and state requirements, costs (permitted charges and reimbursement), and approaches to policies and template consent forms

E. Academic Medical Centers Investing in Innovation *(repeat)*

H. Legal Ethics: The Grey Zone–Ethical Issues in between Compliance and Legal *(repeat)*

1:45-2:45 pm

F. Health Equity and Community Benefit; Tax-Exempt Status for Hospitals *(repeat)*

I. Recycle, Recycle, Recycle: Key Considerations for Research, Medical Education, and Other Secondary Uses of Data *(repeat)*

M. Don't Put the Car-T before the Horse: Proper Planning for Novel Gene Therapies in an Uncertain Regulatory Environment *(repeat)*

Adjournment

Thursday, January 24, 2019

7:00 am-5:15 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.)

8:00-10:30 am General Session

8:00-8:15 am
Welcome and Introduction
Niccolini, Pierce

8:15-9:30 am
Building On #MeToo to Enhance the Learning Environment in U.S. Medical Schools
Colecchia (Moderator), Antman, Gold

9:30-10:30 am
Startup Companies and Institutional Opportunities and Risks
Crowell

10:45 am-12:00 noon Extended Sessions

A. Year in Review–Research Regulations, Investigations, and Hot Topics (not repeated)	B. Physician Comp under the *Qui Tam* Microscope–A Case Study	C. Opposites Attract: New Relationships between AMCs and Managed Care Organizations
Nichols Rusczek	Diesenhaus (Moderator) Jordan Oberembt	Baxter Chesley Leech

12:00 noon-1:15 pm

Lunch on your own or attend the Academic Medical Centers and Teaching Hospitals and Life Sciences Practice Groups Luncheon, *sponsored by PYA*
Topic: The Changing Health Care Landscape: Observations from a Reporter on the Hill
Leonard
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Thursday, January 24, 2019 continued

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D. Impact of the European Union's General Data Protection Regulation on Research Conducted at U.S. Academic Medical Centers (not repeated) Marty Peloquin	**E. Academic Medical Centers Investing in Innovation** Livingston Solomon	**F. Health Equity and Community Benefit; Tax-Exempt Status for Hospitals** Alberti Davis
2:45-3:45 pm		
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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 welcome.)*		

Friday, January 25, 2019

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Planning Committee

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Susan Solomon
Deputy General Counsel
American Hospital Association
Chicago, IL

Maureen Testoni
Interim President and Chief Executive Officer
340B Health
Washington, DC

David J. Vernon
Hooper Lundy & Bookman PC
Washington, DC

Leah A. Voigt
VP, Chief Privacy & Research Integrity Officer
Spectrum Health System
Grand Rapids, MI

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