



AMERICAN BAR ASSOCIATION

Health Law Section



The American Bar Association Health Law Section in conjunction with the Chicago Medical Society present

Healthcare Delivery & Innovation Conference

September 26-27, 2024

Fairmont Millennium Park, Chicago

ambar.org/hdi2024

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SCHEDULE-AT-A-GLANCE

Thursday, September 26, 2024

8:15 am – 8:30 am	Opening Remarks
8:30 am – 9:15 am	KEYNOTE: Physician Litigation Support: Time for a New Paradigm
9:20 am - 10:20 am	What Every Healthcare Provider Needs to Know about Whistleblowers and Mitigating Recovery Liability
10:35 am - 11:35 am	Recent Legal Developments in Reproductive Health Delivery
11:40 am - 12:40 pm	Balanced Innovation: Regulatory Landscape of AI and Digital Health
12:45 pm – 2:00 pm	Lunch on your own
2:05 pm – 3:05 pm	ETHICS: Health Care Privacy is a Hot Mess
3:10 pm – 4:10 pm	Managing Financial Relationships with Providers: A Deep Dive
4:15 pm – 5:00 pm	View from the Chicago Medical Society: Hot Topics Affecting Physicians
5:00 pm – 7:00 pm	Networking Reception with hors d'oeuvres and entertainment!

Friday, September 27, 2024

8:15 am – 9:00 am	Impact of Private-Equity-Owned Physician Staffing Organizations on Patient Safety, Patient Care and Physician Workforce: A Case Study
9:05 am – 9:50 am	Healthcare Has a Math Problem: Evaluating Physician Shortages and Solutions
10:05 am – 10:50 am	Compliant Use of Decentralized or Hybrid Clinical Trial Models
10:55 am - 11:55 pm	Navigating the CMS Value-Based Care Evolution & Innovation Center Strategy
11:55 am– 12:55 pm	Ticketed Lunch – OIG Update *this is a non-CLE session*
1:00 pm – 2:00 pm	Extrapolation in Billing and Coding Audits: Pitfalls and Harbors
2:05 pm – 3:05 pm	The Grass Is Greener - Expanding Access to Alternative Therapies

CONFERENCE AGENDA

Thursday, September 26, 2024

7:30 am - 4:00 pm **Registration Desk Open**

7:30 - 8:30 am **Continental Breakfast**

8:15 – 8:30 am **Welcome to HDI 2024!**

Matt Fisher, Chair
ABA Health Law Section

Tariq H. Butt, MD, President
Chicago Medical Society

8:30 – 9:15 am

**KEYNOTE: Physician Litigation Support:
Time for a New Paradigm**

Many doctors are completely unprepared for litigation, even though the majority will experience it during their careers. The experience is shrouded in secrecy and shame, and the individual physician often suffers in isolation, sometimes with disastrous consequences. Gita Pensa, M.D., will discuss the complexities of litigation stress in doctors, its impact beyond legal outcomes, and how education and more effective support strategies for defendants can mitigate its impact. A significant amount of reimbursement is at risk due to the regulatory changes.

- Identify the origins of litigation stress in the physician defendant.
- Recognize the ways in which litigation stress and fear of litigation drive career abandonment, burnout, and suicide in physicians.
- Explore the role of effective peer support, coaching, and education in mitigating litigation stress.

Speaker:

- **Gita Pensa, M.D. FAAEM**, Adjunct Associate Professor, Department of Emergency Medicine, Brown University, Providence, RI

9:20 – 10:20 am

What Every Healthcare Provider Needs to Know about Whistleblowers and Mitigating Recovery Liability

Healthcare professionals should know that whistleblowers represent the vast majority of recoveries, according to Department of Justice statistics. The presentation will discuss the history and relevant healthcare cases involving whistleblowers, including the qui tam career of Cecilia Guardiola, a registered nurse with a law degree who has been paid awards from three different healthcare institutions. In addition, the presentation will address best practices for responding to whistleblowers and law enforcement agencies investigating their allegations.

Learn from a former federal prosecutor and a national healthcare consulting practice lead how to leverage data analytics in defending government actions, as well as using in proactive compliance activities.

Obtain tips on conducting internal audits/investigations and responding to external ones. Gain a better understanding of how regulators use data to identify and target providers for suspicious behavior. Learn leading practices to help avoid or mitigate government actions. Attendees will learn:

- The significance of whistleblowers.
- The historical context and significant healthcare cases involving whistleblowers.
- Best practices for healthcare organizations to effectively respond to whistleblowers and navigate investigations initiated by law enforcement agencies based on whistleblower allegations.

Speakers:

- **Anthony “Tony” Box**, Partner, Gray Reed & McGraw, Dallas, TX
- **Hilary Harlan, BSRN, JD**, Managing Director, Stout, Philadelphia, PA
- **Sean McKenna**, Partner, Nelson Mullins, Plano, TX

10:20 – 10:35 am

Break

10:35 – 11:35 am

Recent Legal Developments in Reproductive Health Delivery

This session will begin with a brief reminder of the history of reproductive decisions on a federal level including *Roe v. Wade*, *Planned Parenthood v. Casey*, and most recently *Dobbs v Jackson Women's Health Organization*. The session will cover the recent legislative and court decision implications on reproductive healthcare delivery, including fertility and other reproductive health providers. The session will end with some practical ideas for navigating the changing landscape of reproductive health in the differing legal landscapes in the country. This presentation will cover:

- The real-world impacts of court decisions on reproductive healthcare providers.
- How to help providers and their counsel understand how to navigate their jurisdiction's legal landscape surrounding reproductive healthcare.
- What the future may hold for reproductive health providers and regulations governing their practice.

Speakers:

- **Ellee Cochran**, Partner, Husch Blackwell LLP, Austin, TX
- **Gail Deady**, Senior Staff Attorney, Center for Reproductive Rights, New York, NY

11:40 – 12:40 pm

Balanced Innovation: Regulatory Landscape of AI and Digital Health

The integration of artificial intelligence (AI) in healthcare is not just an innovation; it can be transformational. With AI's ability to analyze big data sets, it can dramatically improve patient outcomes, reduce costs, and enhance operational efficiencies. Further, AI is frequently integrated into digital health solutions to enhance their capabilities. The use of AI technologies in digital health presents a unique set of legal challenges. This presentation aims to explore these challenges, focusing on privacy concerns, regulatory compliance, liability issues, and the ethics of AI decision-making in healthcare. Attendees will understand:

- The use of AI in healthcare.
- Legal challenges and the regulatory landscape.
- Liability and ethical considerations
- Navigating the future.

Speakers:

- **Kelly Greening**, Associate General Counsel, Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL
- **Megan Harkins**, Associate General Counsel, VillageMD, Berkeley Heights, NJ
- **Andrea Linna**, Partner, Wilson Sonsini, Palo Alto, CA

12:45 – 2:00 pm

Lunch on your own

2:05 – 3:05 pm

ETHICS: Health Care Privacy is a Hot Mess

Healthcare privacy is a hot mess. There is an increasingly complicated set of laws and regulations impacting how health data can be used in and out of the core system. These rules are confusing, overlapping and often borderline incomprehensible, yet lawyers working in this area have an ethical duty of competence. At the same time—particularly for innovative uses of healthcare technology—there is an increased risk of enforcement and growing concerns about the impact of these rules on a wide range of valuable technology. Business associates, including lawyers holding HIPAA data, have a duty to understand data security risks. Despite these complexities, there are societal benefits and business opportunities for using health data in thoughtful and appropriate ways consistent with these evolving legal requirements. Attendees will come away with:

- An understanding of key, recent developments affecting healthcare privacy and legal considerations for providers, payors, lawyers, and other entities that handle health data.
- The ability to evaluate options for addressing privacy compliance, both for your business and in the regulatory system.
- Information regarding finding value in health data in a manner that navigates legal considerations and risks.

Speakers:

- **Ebunola Aniyikaiye**, Assistant General Counsel & Sr. Director of Policy & Regulatory Affairs, Homeward Health, San Francisco, CA
- **Kirk Nahra**, Partner, WilmerHale, Washington, DC
- **Andrew Rusczek**, Epstein, Becker & Green, Boston, MA

3:10 – 4:10 PM

Managing Financial Relationships with Providers: A Deep Dive

Join us for an insightful presentation that delves into the intricate landscape of managing financial arrangements with healthcare providers. This session will center around a comprehensive report, shedding light on data that unveils how organizations navigate the complexities of provider compensation. We will focus on key settlements that underscore the critical need for appropriate management in this domain. Understand options and rights when faced with a government inquiry. Attendees will:

- Gain valuable insights from a detailed report on how healthcare organizations approach and manage provider compensation.
- Explore industry trends, challenges, and successful strategies that have emerged in this critical financial area.
- Delve into key settlements that underscore the importance of vigilant and compliant management of financial arrangements with providers.

Speakers:

- **Alex Krause**, Associate General Counsel, Parkview Health, Fort Wayne, IN
- **Richard Romero**, Senior Vice President, Coker Group, Brentwood, TN

4:15 – 5:00 pm

View from the Chicago Medical Society: Hot Topics Affecting Physicians

Physicians practicing in the Chicagoland area face many challenges that impact their delivery of healthcare services. Challenges impacting physicians in Chicago include healthcare workforce shortage issues and physician burnout, the impact of the COVID-19 pandemic, physician employment by health systems and insurance companies, and many other critical challenges. The speakers will address these and other issues having a significant effect on physicians. Attendees will learn to:

- Understand current challenges faced by hospitals and physicians affecting the delivery of health care services.
- Identify issues that hospitals and physicians are anticipating for the future.

- Identify strategies hospitals and physicians are implementing to address these challenges.

Speakers:

- **Tariq Butt, M.D.**, President, Chicago Medical Society, Chicago, IL
- **Vishnu Chundi, M.D.**, Metro Infectious Disease Consultants, LLC, Chicago, IL
- **Clay Countryman**, Breazeale Satche, Baton Rouge, LA

5:00 – 7:00 pm

Networking Reception

Enjoy a chance to relax, network with colleagues, and meet our speakers, other members of the ABA Health Law Section, and the Chicago Medical Society over drinks, food, and live entertainment!

Friday, September 27, 2024

8:15 – 9:00 am

Impact of Private Equity-Owned Physician Staffing Organizations on Patient Safety, Patient Care, and Physician Workforce: A Case Study

Private equity firms have deepened investments in the health care sector in recent years, particularly in staffing firms, on which many U.S. hospitals have come to rely. In March 2024, the U.S. Department of Justice and other federal agencies launched a probe to examine whether private equity interests are damaging healthcare workers, quality of care, and affordability. The panel will discuss private equity’s impact on the economically challenged U.S. health care delivery system. Specifically, the panel will discuss private equity’s effect on patient care models and the physician workforce, which, in the view of a not-insignificant number of physicians, has led to patient safety and quality concerns as well as questionable/aggressive billing practices. The panel will provide a case study and real-time examples of such practices. Attendees will learn to:

- Recognize the operational realities faced by hospitals that support the engagement of PE-backed firms to meet their staffing needs.
- Identify the opportunities and challenges doctors and APPs face when hospitals choose this staffing model.
- Recognize the legal issues raised for the hospitals and affected physicians and APPs.

Speakers:

- **Carey F. Kalmowitz, Esq.**, The Health Law Partners, Farmington Hills, MI
- **Ted Kanellakes**, Chicago Medical Society, Chicago, IL

9:05 – 9:50 am

Healthcare Has a Math Problem: Evaluating Physician Shortages and Solutions

In a post-pandemic era, there is a growing crisis lurking - patient needs far outweigh physician supply. With a focus on the specialty of cardiology, this program will outline the existing physician shortage problem, and discuss why the problem continues to grow, including burnout, demographic shifts in new workforce entrants, and other underlying problems. This session will offer potential solutions and associated legal pitfalls. This session will:

- Provide a clear view of physician shortage projections.
- Increase understanding of continuing physician shortages and worsening patient access.
- Evaluate possible solutions to consider when addressing growing care gaps.

Speaker:

- **Katy Pollitt (Baum)** Associate, Katten Muchin Rosenman, Chicago, IL

9:50 – 10:05 am

Break

10:05 – 11:50 am

Compliant Use of Decentralized or Hybrid Clinical Trial Models

This session will explore the rise of decentralized clinical trials, FDA's regulation of such trials, and how digital health products and telemedicine are leveraged for use in these clinical trial models. Specific attention will be paid to investigator responsibilities, sponsor responsibilities, use of local healthcare providers, and compliant use of digital health products and telemedicine. This session will help attendees:

- Understand the responsibilities of principal investigators and sponsors when conducting a decentralized clinical trial.
- Understand the importance of compliant use of telemedicine and key considerations.
- Contemplate key contractual considerations when negotiating a decentralized clinical trial agreement.

Speaker:

- **Monica Chmielewski**, Vice-Chair Healthcare Practice, Foley & Lardner, Chicago, IL

10:55 – 11:55

Navigating the CMS Value-Based Care Evolution & Innovation Center Strategy

This session will explore the CMS Innovation Center (CMMI) strategy refresh, emphasizing health system transformation. Key points include five strategic objectives for Advancing System Transformation in CMMI's second decade, drawing on lessons from the first. It will delve into expanding models, reducing costs, enhancing outcomes, and promoting health equity, with a focus on recent initiatives like GUIDE and Making Care

Primary. The presentation will highlight CMMI's innovative approach to creating value-based care (VBC) opportunities, targeting areas traditionally challenging within Medicare FFS. Attendees will:

- Obtain an understanding of the CMS Innovation Center (CMMI) overall VBC strategy.
- Identify lessons learned from existing programs while learning about the new efforts and programs of CMMS in the Medicare FFS VBC space.
- Identify CMMI value-based opportunities and approaches for your organization.
- Formulate strategies to leverage physician relationships and optimize care delivery in your organization's move towards value-based care in Medicare FFS.

Speakers:

- **Ellen Brown**, Partner, BP2 Health, Jupiter, FL
- **Jim Daniel**, Partner, Hancock, Daniel & Johnson, P.C., Richmond, VA

11:55 am – 12:55 pm

Ticketed Lunch

OIG Update – David Fuchs

This is a non-CLE session

1:00 – 2:00 pm

Extrapolation in Billing and Coding Audits: Pitfalls and Harbors

Since the end of the public health emergency (PHE), healthcare providers have experienced a significant increase in both the quantity and aggressiveness of billing/coding audits simply because the payers must make up for the time during the PHE that audits were suspended. Extrapolation has resulted in a massive increase in overpayment demands with almost no increase in effort. What we are witnessing is a virtual feeding frenzy, and healthcare providers are the prey. This presentation will provide comprehensive guidance on understanding the process, challenges and strategies involved in successfully defending all types of payer audits. This session will cover:

- The Medicare extrapolation audit process, including key stages, timelines, and response requirements.
- Practical defense strategies tailored to challenging extrapolation audit findings including key proactive measures, documentation best practices, and leveraging statistical expertise.
- The intricacies of the appeals process, including understanding levels of appeal, deadlines, and essential documentation for effective audit outcomes.

Speakers:

- **Stephen Bittinger**, Partner, K&L Gates, Washington, DC
- **Frank Cohen**, Senior Director, VMG Health, Dallas, TX
- **Mary Malone**, Partner, Hancock, Daniel & Johnson, Richmond, VA

2:05 – 3:05 pm

The Grass Is Greener - Expanding Access to Alternative Therapies

Medical marijuana is legal in 38 states. This session will explore the always-evolving regulatory structure for medical marijuana. Using Louisiana as a guidepost, the panelists will discuss issues related to scope and expansion, patient access, legislative advocacy, and product and program improvement. Such topics and issues will be useful for all jurisdictions and are relevant as states contemplate decriminalization of other therapies, such as psilocybin. The speakers will provide unique insight and fun anecdotes on the following:

- Structure of a medical marijuana program (conversion of oversight from the board of pharmacy to the department of health).
- Legislative process (including ongoing lobbying efforts to continually improve the program).
- "Going live" (stories from the frontlines: dispensing to first patient in Louisiana and to first veteran patient in Louisiana).
- Physician and healthcare provider engagement.
- Evolution of medical marijuana product offerings and treatable conditions.
- Potential for decriminalization of other therapies, such as psilocybin.
- Research and telehealth.

Speakers:

- **David “Beau” D. Haynes, Jr.** Partner, Phelps Dunbar, New Orleans, LA
- **Randy J. Mire, Pharm D,** Founder & CEO, Capitol Wellness Solutions, LLC, Baton Rouge, LA
- **Lovie Rodgers, Pharm D, MPH,** CEO, Crescent City Therapeutics, LLC, Kenner, LA

CONFERENCE & CLE INFORMATION

REGISTRATION

Online: ambar.org/HDI2024

US MAIL

American Bar Association
Health Law Section
ATTN: Service Center/Meeting/Event
Registrations Department
321 N. Clark Street
Chicago, IL 60654

Register by August 22, 2024 online to receive the early bird registration rates, by US Mail, or online. Registration will be accepted only when accompanied by a check, money order, Visa, American Express, or MasterCard information. Registrations will not be held without payment. Your payment will cover admission to the program, continental breakfasts, coffee breaks, conference luncheon, receptions and one set of program course materials.

CANCELLATION POLICY

A refund will be issued upon **written cancellation received no later than September 18, 2024**, minus a \$75 handling charge for each registration. Cancellations received after this date cannot be refunded but substitutions are encouraged. The ABA reserves the right to cancel any program and assumes no responsibility for personal expenses.

HOTEL INFORMATION

The conference will be held at the Fairmont Chicago - Millennium Park, 200 North Columbus Drive Chicago, IL 60601. When making reservations by phone or online, please mention the ABA Health Law Section Healthcare Delivery & Innovation Conference to secure the group rate of \$299 for a standard room. **This special rate expires Wednesday, September 4, 2024.** A limited number of government-rate rooms have been reserved on a first available basis. Please note the GSA may change the government rate at any time, so please confirm the rate with the hotel when booking. [Book your room here!](#)

CLE CREDIT

The ABA will seek 12 hours of CLE credit in 60-minute states, and 14 hours of CLE credit for this program in 50-minute states. Credit hours are estimated and are subject to each state's approval and credit rounding rules.

Please visit americanbar.org/mcle for general information on CLE at the ABA. Credit is not available for on-demand courses within the platform, though accredited on-demand courses may be available separately.

CME Information

Physicians that attend this conference may earn CME credits. For additional information about this CME activity, including any updates regarding faculty members and/or commercial support disclosures, please visit the Chicago Medical Society's (CMS) website at www.cmsdocs.org. You may also contact the CMS Education Department at cms@cmsdocs.org or via phone at 312-670-2550.

Healthcare Delivery & Innovation Conference has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education

(ACCME) through the joint provider ship of the Chicago Medical Society, the American Bar Association's Health Law Section, and the American Association for Physician Leadership. The Chicago Medical Society is accredited by the ACCME to provide continuing medical education for physicians. The Chicago Medical Society designates this live activity for a maximum of 16 PRA Category 1 Credit(s)[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

AIRLINE INFORMATION

ABA NEGOTIATED AIRFARE DISCOUNTS – AVAILABLE ONLINE FOR ABA MEMBERS!

*A Travel Profile is required when booking airline reservations with ABA Egencia

HEALTH LAW SECTION MEMBERSHIP

As a bonus, the member's tuition rate will be available to registrants who become new members of the ABA Health Law Section. Membership dues are not deductible as charitable contributions for federal income tax purposes, but such dues may be deductible as a business expense. American Bar Association membership is required to become a member of the Health Law Section.

TAX DEDUCTION FOR EDUCATIONAL EXPENSES

An income tax deduction may be allowed for educational expenses undertaken to maintain or improve professional skills. This includes registration fees, travel, meals, and lodging expenses. (See Treas. Reg. 1.162-5) (Coughlin vs. Commissioners, 203 F. 2d 307).

SERVICES FOR PERSONS WITH DISABILITIES

If special arrangements are required for an individual with a disability to attend this program, please contact the Health Law Section staff at (312) 988-5708 or danielle.daly@americanbar.org.

DRESS CODE

Business attire, including business casual, is appropriate for all meetings, CLE programs, and social events during the program.

SCHOLARSHIP

Financial scholarship applications are available for this conference. To request an application or receive additional information, please contact Danielle Daly (danielle.daly@americanbar.org). **Deadline for receipt: August 30, 2024**, no cases will be considered after the deadline, and all standard registration fee rates will apply after August 30, 2024.

REGISTRATION

Online: ambar.org/HDI2024

REGISTRATION FEES	Full Conference Early Bird Price:	Full Conference Price:
Health Law Member	\$670	\$770
ABA Member, Non-Health Law Section Member	\$725	\$825
Non-Member	\$920	\$1020
In-House Counsel / Solo Practitioner / Government / Academic / Physician (full-time only)	\$350	\$350
Law Student	\$50	\$50
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TOTAL FEES ENCLOSED		

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UPCOMING EVENTS

October 16-18, 2024 – False Claims Act Mock Trial Institute | DC Court of Appeals Historic Courthouse

November 7-8, 2024 – Managed Care Institute | Norton Rose Fulbright, New York, NY

December 9-10, 2024 – Washington Health Law Summit | The Ritz-Carlton Hotel, Washington, DC

April 2-5, 2025 – 26th Annual Emerging Issues in Healthcare Law Conference | Hyatt Regency, Long Beach, CA