

connections

For the health and life sciences law community



Regulating the Future of Artificial Intelligence (page 10)

More Data Please! The Challenges of Applying Health Information Privacy Laws to the Development of Artificial Intelligence (page 16)

Medical Frontiers in AI Liability (page 22)

ANNOUNCING Health Law Week

With the landscape continuing to shift around delivery of care in the U.S. health care system, the health law professional is at the center, providing analysis, assessing risk, ensuring compliance, and making recommendations to their organizations and clients to protect them from liability. They are the stabilizing force within the industry and AHLA wants to celebrate and champion these professionals!

Health Law Week is about increasing awareness of this integrated and integral profession within the health care industry, highlighting programs that create new opportunities for entry into the profession, showcasing organizations/firms dedicated to employing these professionals, and elevating this community's contributions to the health care industry. This is a celebration of the individual and magnification of the collective community.



Monday, April 27

Craft Los Angeles

10100 Constellation Boulevard
Los Angeles, CA 90067



Tuesday, April 28th

Harper's Garden

31 South 18th Street
Philadelphia, PA 19103



Wednesday, April 29th

Malt House Cellar Room

2017 Chouteau Avenue
St. Louis MO 63103



Thursday, April 30th

McCormick & Schmick's Washington, DC

1652 K Street, NW
Washington, DC 20006

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Thank you to our Health Law Week Partner for their generous support:



A Multitude of Voices: Why Diversity and Inclusion Benefits AHLA

"The diversity agenda for me is understanding the power of nuances....I'd rather have 12 different people sitting at the table with me, all with worldviews – all clear that we're going to solve a common problem." – Bernard Tyson, Former CEO, Kaiser Permanente

As current AHLA President Rob Niccolini wrote in the January issue of *Connections*, this past June AHLA created the Membership Diversity+Inclusion (MDI) Committee as a Board-level Committee to ensure AHLA's governance structure incorporates our value of ensuring Diversity+Inclusion (D+I).

As the first Chair of MDI, I find the words of the recently deceased Mr. Tyson to be very illustrative of the value of being inclusive. I agree with Mr. Tyson. The health law profession is all about interpreting the grey. Therefore, by ensuring inclusion in our discourse we enrich the interpretation. We are more powerful when we consider the nuances and different perspectives in solving the issues faced by the health law industry.

Kaiser Permanente's general counsel, Mark Zemelman, spoke to AHLA's Board of Directors a few years ago about how Kaiser Permanente factors in D+I from the top down and in many facets of its activities. Similarly, the AHLA Board views D+I as crucial to the Association's future like other Board initiatives and as a key area of focus across all activities of the Association. By creating MDI, AHLA strengthens several membership strategies, including D+I, to ensure inclusive speakers, authors, and volunteer leaders. We are looking at inclusion from different angles to find solutions. The nuances make the difference.

AHLA is fortunate to have Board Directors who represent academia; small, medium, and large law firms; associations; the federal government; pharmaceutical organizations; for profit, academic and not-for-profit health systems; and payers. We have each experienced the world in a different manner and have varying perspectives. Each of my fellow Board colleagues adds something to the discourse.

The Association's strategies on advancing D+I initiatives have evolved tremendously since I served on its D+I Council nine years ago. It is a value system rooted in AHLA. Recently, members of the Board were asked to complete a sentence about D+I (see box below). Everyone responded, and I selected 12 representative responses, from varying walks of the health law industry and different worldviews, to illustrate why our AHLA community benefits by sponsoring inclusion and embedding it in our DNA.

My 12 colleagues' responses below demonstrate that each of us on the Board takes responsibility for ensuring inclusion and why all members of the AHLA community need to consider



the benefits of inclusion in their activities across the scope of AHLA and in their professional endeavors. We need the nuances. It does not diminish our quality, but rather it empowers our critical thinking, analysis, and problem solving. It makes us a more effective association and community. **C**

Dawn R. Crumel, Vanderbilt University Medical Center; Chair, Membership Diversity + Inclusion Committee, AHLA

I believe diversity and inclusion benefits AHLA because...

"Ability and insights are available from everyone and different perspectives are particularly useful. We won't get the benefit of everyone's skills and knowledge unless we are diverse and inclusive." *Marilyn Lamar, Liss & Lamar*

"We are enriched as an association by having members and leadership with diverse backgrounds and views." *Greg Demske, HHS Office of the Inspector General*

"It allows us to consider various perspectives, to recruit and retain a broad range of talent, and to be relevant and competitive in the field." *Maryam Khotani, Pharmacyclics*

"The Association is strong when it is inclusive and welcoming to all health law professionals." *Craig Holden, Baker Donelson*

"It allows us to make full use of the different backgrounds, perspectives, and experiences of our members, leaders, and employees. It is a critical source of our strength and resiliency because it makes us more dynamic, collaborative, and innovative." *Christine White, Northwell Health System*

"AHLA can effectively fulfill its mission only by being a true reflection of the various professional communities it serves, in their totality." *Linda Moroney, Manatt Phelps & Phillips*

"We are all enriched when we appreciate the differences in our members." *Cindy Reisz, Bass Berry & Sims*

"It makes us a better association of health care legal experts able to respond to the needs of our diverse membership, communities, and nation now and in the future." *Kirk Dobbins, Kaiser Permanente*

"We need diverse experience and inclusion of diverse perspectives to see our problems and their solutions." *Jennifer Evans, Polsinelli*

"It helps us emerge from group-think, exposes us to new ideas and perspectives, and reduces barriers to membership and engagement in AHLA." *Mark Kopson, Plunkett Cooney*

"Diversity and inclusion lead to more innovation, more opportunities for all, better access to talent, and better performance as an Association providing value to its members." *Hal McCard, Quorum Health Corporation*

"We are at our best as an organization when all voices are heard, and everyone has a seat at the table." *Rob Niccolini, Ogletree Deakins Nash Smoak & Stewart*

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- 16** **More Data Please! The Challenges of Applying Health Information Privacy Laws to the Development of Artificial Intelligence**
Adam Greene discusses privacy issues for PHI in the context of AI.



- 22** **Medical Frontiers in AI Liability**
Danny Tobey and Allie Cohen analyze some of the emerging liability issues for AI at key points where systems interact and responsibilities are divided or unclear.

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NETWORK.
ENGAGE.**



**DEADLINE
APPROACHING**

Health Care Transactions

April 20-22, 2020

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AHLA Board of Directors

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Expert Insights Podcasts

Four New Podcasts Available

Fraud and Abuse: 2020 Outlook

In our newest monthly series, Matthew Wetzel, Senior Counsel, Akin Gump Strauss Hauer & Feld LLP, Kevin Raphael, Partner, Pietragallo Gordon Alfano Bosick & Raspanti LLP, and BRG discuss hot topics and key developments in health care fraud and abuse. *Sponsored by Berkeley Research Group LLC (BRG).*

2020 Outlook for Teaching Hospitals and Academic Medical Centers

New podcasts in our Expert Insights podcast series take an in-depth look at some of the key sessions from AHLA's 2020 Academic Medical Centers and Teaching Hospitals Institute in Arlington, VA. Listen to subject matter experts discuss what in-house and outside counsel who advise teaching hospitals and academic medical centers need to know. *Sponsored by Coker Group.*

Launching your Career in Health Law

Nothing is more important to your career than where you work. AHLA's latest podcast series will be invaluable to any law student or law firm summer associate. Thomas Wronski, of Thomas Wronski and Associates, a national legal search consulting firm, in Part 1 of the series, speaks with Amy Simmons, Director of Attorney Recruitment & Professional Development at Epstein Becker Green, about the law firm hiring process and pursuing a career in health law. *Sponsored by Thomas Wronski and Associates.*

2019's Biggest Antitrust Developments and what to expect in 2020

In a sequel to their popular podcast last year, John D. Carroll of King and Spalding LLP and Alexis J. Gilman of Crowell and Moring LLP detail 2019's biggest antitrust developments and highlight what attorneys should expect in 2020. *Sponsored by HealthCare Appraisers Inc.*

Listen to these podcasts today!



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Speak
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at AHILA.
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AHLA

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AHLA CONNECTIONS

1620 Eye Street NW, 6th Floor,
Washington, DC 20006-4010
202.833.1100
connections@healthlawyers.org
www.healthlawyers.org/connections

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Samantha Roesler, MCI Group
410.584.1996
samantha.roesler@mci-group.com
www.ahla-mediaplanner.com/

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MISSION

The Mission of the American Health Lawyers Association is to provide a collegial forum for interaction and information exchange to enable its members to serve their clients more effectively; to produce the highest quality non-partisan educational programs, products, and services concerning health law issues; and to serve as a public resource on selected health care legal issues.

AHLA DIVERSITY+INCLUSION STATEMENT

In principle and in practice, the American Health Lawyers Association values and seeks to advance and promote diverse and inclusive participation within the Association regardless of gender, race, ethnicity, religion, age, sexual orientation, gender identity and expression, national origin, or disability. Guided by these values, the Association strongly encourages and embraces participation of diverse individuals as it leads health law to excellence through education, information, and dialogue.

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- Carol Hay, Esq.



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Connections to Learning

February

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2020 Telemedicine Webinar Series, Part III: Telemedicine Reimbursement: Medicare, Medicaid, and Commercial Coverage

10-12

Physicians and Hospitals Law Institute

Sheraton Grand Phoenix
Phoenix, AZ

Platinum Sponsor: HORNE LLP

Gold Sponsor: PYA, SullivanCotter

Silver Sponsor: HMS Valuation Partners, JTaylor

- Feb 10—Luncheon, hosted by Physician Organizations Practice Group
- Feb 10—Luncheon, hosted by Health Care Liability and Litigation, In-House Counsel, Labor and Employment, and Medical Staff, Credentialing, and Peer Review Practice Groups
- Feb 11—Networking Breakfast and Presentation, hosted by AHLA's Women's Leadership Council, sponsored by Pinnacle Healthcare Consulting
- Feb 11—Luncheon, hosted by Health Information and Technology Practice Group

- Feb 11—Luncheon, hosted by Hospitals and Health Systems Practice Group, sponsored by Affiliated Monitors

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2020 Telemedicine Webinar Series, Part IV: Structuring and Payment for Remote Patient Monitoring Services

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Autism and Other Emotional and Intellectual Disability Services: Current Transactions, Reimbursement Landscape, and Landmark Litigation

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Physician Practices: Strategies for Remaining Independent

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Payers, Plans, and Managed Care Practice Group Educational Call

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The Opioid Crisis and Compliance
sponsored by Protiviti

24

Life Sciences Practice Group Educational Call

25

AI and Health Law, Part I: Overview - Myth Versus Reality
sponsored by Nuance

26

Compensation Under Management Agreements for Joint Ventures

27

Federal False Claims Act: A Year in Review

March

2-4

Long Term Care and the Law

Grand Hyatt San Antonio
San Antonio, TX

PYA has provided sponsorship in support of this program.

- Mar 3—Luncheon, hosted by Post-Acute and Long Term Services Practice Group, sponsored by JTaylor



Educational Call: Free live virtual event open to AHLA Practice Group members only. CLE credits not offered.



In-Person Program: Paid multi-day conference open to AHLA members and non-members. Includes educational sessions and networking receptions. CLE credits offered.



Webinar: Paid live virtual event open to AHLA members and non-members. CLE credits offered.



Networking Event



Volunteer Opportunity

For more information on all AHLA events and to register, go to www.healthlawyers.org/events or call (202) 833-1100, prompt #2.

25-27

Institute on Medicare and Medicaid Payment Issues

Baltimore Marriott Waterfront Hotel
Baltimore, MD

PYA has provided sponsorship in support of this program.

- Mar 20—Luncheon, hosted by Regulation, Accreditation, and Payment Practice Group, sponsored by HORNE LLP



- April 21—Networking Breakfast and Table Topic Discussions, hosted by AHILA's Women's Leadership Council
- April 21—Luncheon, hosted by Business Law and Governance Practice Group, sponsored by Lovell Communications

April

20-22

Health Care Transactions

JW Marriott Nashville
Nashville, TN

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27-30

Health Law Week

- April 27—Craft Los Angeles, Los Angeles, CA
- April 28—Harper's Garden, Philadelphia, PA
- April 29—Malt House Cellar Room, St. Louis, MO
- April 30—McCormick & Schmick's, Washington, DC



May

4-6

Mediation Training

Attune
Washington, DC



June

28

In-House Counsel Program

Manchester Grand Hyatt
San Diego, CA

Ntracts has provided sponsorship in support of this program.



29-July 1

Annual Meeting

Manchester Grand Hyatt
San Diego, CA



JOIN THE DISCUSSION

We look forward to
hearing from you
in the Communities!

[www.healthlawyers.org/
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Member Service

Volunteer Recognition: November 2019

AHLA has a wonderful tradition of members sharing their expertise and insight with each other. Members generously donate their time and energy through speaking, writing, and other service to the organization. Volunteers are the heart of the Association—thank you for all you do!

PROGRAMS AND DISTANCE LEARNING

In-Person Programs

Fundamentals of Health Law

Brian C. Betner, *Hall Render Killian Heath & Lyman PC*
Anthony H. Choe, *Polsinelli PC*
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Health Plan Law and Compliance Institute

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Dorothy De Angelis, *Ankura Consulting*
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Jeremy Earl, *McDermott Will & Emery LLP*
Paul Eiting, *Blue Cross Blue Shield Association*
David Ellenbogen, *Scott & White Health Plan*
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Educational Calls

Payers, Plans, and Managed Care Practice Group Educational Call
Stephen P. Mahinka, *Morgan Lewis & Bockius LLP*

Transactions Affinity Group Educational Call

Kate L. Bechen, *Husch Blackwell LLP*
Vipul Patel, *Aon Strategic Advisors and Transaction Solution*
Jed A. Roher, *Godfrey & Kahn SC*

Regulation, Accreditation, and Payment Practice Group Educational Call

Monica Dang
Jenniffer Harlow, *CMS/CMMI*
Pauline Lapin
Katrina A. Pagonis, *Hooper Lundy & Bookman PC*
Perry Payne, *CMS/CMMI*
Paul Trompke
Judith A. Waltz, *Foley & Lardner LLP*
Christine Burke Worthen, *Northern Light Health*

Webinars

Thought Leader Perspectives Webinar—Top 5 Practice Business Issues—What Attorneys Need to Know

Jeffrey T. Gorke, *The Coker Group*

New CMS Program Integrity Final Rule is Here—Guideposts for Operationalizing the New Disclosure Requirements

Colin P. McCarthy, *McGuireWoods LLP*
Ross E. Sallade, *Polsinelli PC*
Jeanne L. Vance, *Salem & Green PC*

The Stark Proposed Rule: Exploring the New FMV, Commercial Reasonableness, and Volume or Value Guidance

Kelly M. Cleary, *U.S. Department of Health and Human Services*
Jennifer Johnson, *VMG Health*
Jason Lee, *ECG Management*
Kimberly A. Mobley, *Sullivan Cotter and Associates Inc*
Charles B. Oppenheim, *Hooper Lundy & Bookman PC*
Joseph N. Wolfe, *Hall Render Killian Heath & Lyman PC*

Rural Health and the Law, Part III: Narrowing the Rural Health Disparity Gap: Success in using ACOs and Integrated Care Models

Brian F. Bauer, *Hall Render Killian Heath & Lyman PC*
Steve Clapp, *Strategic Healthcare Advisers*
Gina Eastin, *Yuma District Hospital & Clinics*
Andrea M. Ferrari, *HealthCare Appraisers Inc*
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Health Information Technology Implications of the AKS and Stark NPRM

Matthew Edgar, *Centers for Medicare & Medicaid Services*
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Protecting Research and Intellectual Property from Theft

Kevin T Carroll, *Wiggin and Dana*
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Joshua Larocca, *Aon*

PUBLICATIONS, RESOURCES, AND PERIODICALS

AHLA Connections

Maintaining Quality and Preserving Privilege for Telemedicine and Other Outsourced Providers

Robin Locke Nagele, *Post & Schell PC*
Elizabeth Margaret Hein, *Post & Schell PC*

Portrait of a Mentoring Relationship, In Two Takes

Anthony Fanucci, *Penn State Dickinson Law*
Jennifer M. Nelson Carney, *Bricker & Eckler LLP*

Health Care Under Fire—Preparing for an Active Shooter Before Your Facility Is a Target

Sarah E. Swank, *Nixon Peabody*

From Construction Law to Health Law: One Young Professional's Journey

Goran Musinovic, *Realty Trust Group LLC*

Inpatient Rehabilitation Facilities Under Review for Medicare Claims That Do Not Meet the “Reasonable and Necessary” Requirement

Michelle Ferrare-Huntsman, *King & Spalding LLP*
Christopher P. Kenny, *King & Spalding LLP*

Successfully Designing and Implementing a Code of Conduct

Marla Susan Berkow, *Gateway Foundation*
Rick Hindmand, *McDonald Hopkins LLC*

AHLA Weekly

HIPAA and the CCPA: What Health Care-Related Organizations Need to Know

Charles E. Harris, *Mayer Brown*
Elizabeth Mann, *Mayer Brown*

Podcasts

Expert Insights: Acting IG Joanne Chiedi on AKS Reform, Technology, and the Future of Enforcement

Joanne Chiedi, *DHHS Office of the Inspector General*

Speaking of Health Law—Expert Insights—Best Practices for IRC 4960

Preston James Quesenberry, *KPMG LLP*

Speaking of Health Law—Expert Insights—Physician/Employee Tax Issues

Cynthia F. Wisner, *Trinity Health*

Speaking of Health Law—Expert Insights—Section 501

Andrew D. Kloeckner, *Baird Holm LLP*

Speaking of Health Law—The Lighter Side of Health Law

Norman G. Tabler Jr. (Ret.), *Faegre Baker Daniels LLP*

Practice Group Briefings

An Analysis of Joint Ventures and Partnerships: Health Care Entities and Private Equity Firms

Alé Dalton, *Bradley Arant Boult Cummings LLP*
Pirjin Tayip Laser, *Waller Lansden Dortch & Davis LLP*

CMS Lowers Physician Supervision Requirement for Outpatient Therapeutic Services in 2020 OPPTS Final Rule

Janus Pan, *Bradley Arant Boult Cummings LLP*

Texas v. U.S.: Potential Impacts on Health Care Innovation and Fraud and Abuse Prevention

Troy A. Barsky, *Crowell & Moring LLP*
Alice Hall-Partyka, *Crowell & Moring LLP*

The Bridge to Blockchain in Health Care: Guidance for Business Lawyers

Kristen Johns, *Waller Lansden Dortch & Davis LLP*
Thejasree Kayam, *Surescripts LLC*

Practice Group Bulletins

CMS Ends “Site Neutral” Transitional Payments for LTCH Discharges Occurring in Fiscal Years 2016 to 2019

Janus Pan, *Bradley Arant Boult Cummings LLP*

Marijuana Use by Patients Creating Challenges for In-House Counsel

Tyler G. Jacobsen, *Samaritan Health Services*

Preventing and Responding to Sex Discrimination in Health Care—Ensuring Compliance with Section 1557 of the Affordable Care Act

Emily Miller, *Seyfarth Shaw LLP*
Leon Rodriguez, *Seyfarth Shaw LLP*

Practice Group Toolkits

State Response to Opioid Crisis and Opioid Prescribing Requirements: A 50 State Survey

Rodney K. Adams, *University of Richmond Law School / Virginia Commonwealth U Dept of Health Administration*

Constance L. Akridge, *Holland & Hart LLP*

Lynn M. Barrett, *Lynn Barrett*

Franklin D. Beahm, *Beahm & Green*

Scott Bloomberg, *Foley Hoag LLP*

Nicole Burgmeier, *OptumRx*

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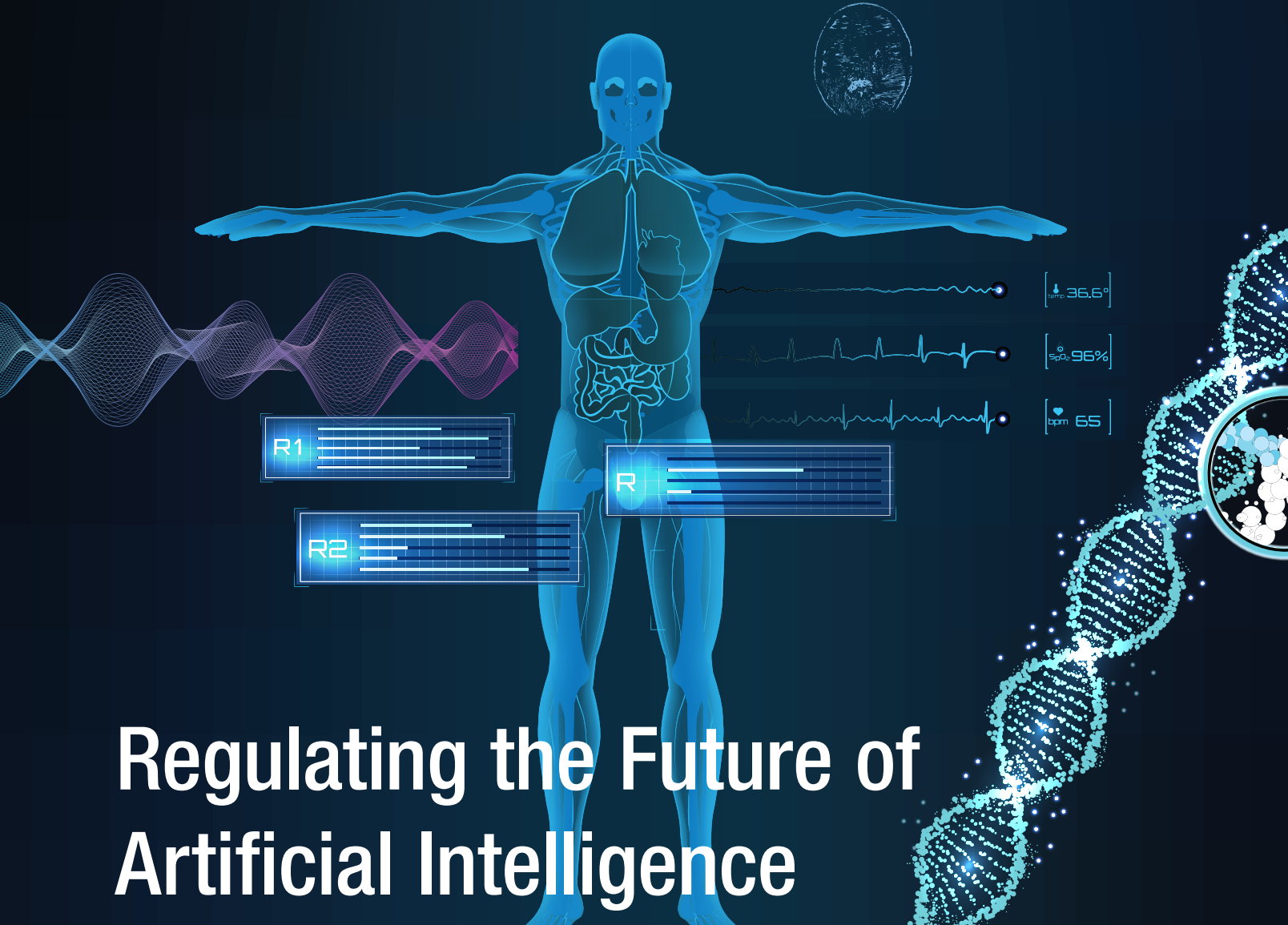
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Regulating the Future of Artificial Intelligence

By Carolyn V. Metnick, McDermott Will & Emery LLP, and Dina B. Ross, Dina B. Ross Law Offices

Artificial intelligence (AI) is becoming a more frequent discussion item among health care providers, clinicians, manufacturers, and developers. With the rise and deployment of AI, we expect to see earlier disease detection, greater diagnostic accuracy, and more tailored treatment plans. The possibilities are beyond our imaginations, and we are only beginning to see the opportunities and potential. Although interest in AI is growing, and the use of AI is becoming more common, the regulatory framework in the United States remains in the nascent stages of development. This article provides an overview of the existing and evolving U.S. federal regulatory framework.

What Is Artificial Intelligence?

AI means different things to different stakeholders, but it is generally and broadly defined as computer engineering that results in the imitation of intelligent behavior or human learning and reasoning. There are different classes of AI. At one end of the spectrum we have impressive but basic reactive machines that store millions of bits of data and can weigh best

options based on that data, but that cannot learn from past mistakes. Computer chess is an example of a reactive machine. At the other end of the spectrum are more sophisticated examples, including machine learning (ML), where a system uses human-programmed algorithms to review data over and over again until it “learns” to determine something or predict an event. A queue of recommended movies based on prior viewing habits is an example of ML. One particularly sophisticated form of ML is deep learning, where a machine “learns” similarly to a human’s neural system. It is fed an enormous amount of data until it piles layers of data together, discovering patterns, pathways, interconnectivities, and relational concepts in the data far beyond what it was programmed to identify. Driverless cars are an example of deep learning.

AI applications in health care typically constitute software as a medical device¹ (SaMD), which is software for one or more medical purposes that performs without being part of a hardware medical device and may run on different operating systems or in virtual environments. The Food, Drug and Cosmetic Act considers medical purposes to be purposes that are intended to treat, diagnose, cure, mitigate, or prevent

disease or other conditions. An example of SaMD is software that allows a smartphone to view images from an MRI. Software that drives or controls the motors and pumping of medication in an infusion pump, however, is not SaMD, as the hardware medical device requires the software to perform its intended use. ML and deep learning AI differ from other SaMD in that each has the potential to adapt and improve quickly and in real time.

The U.S. Food and Drug Administration (FDA) is responsible for the regulatory framework for AI, yet it has encountered challenges and continues to wrestle with the framework for reasons that are as unique as AI itself.

21st Century Cures Act

The 21st Century Cures Act (Act), which was enacted in December 2016, codified that certain digital technologies fall outside the FDA's regulation authority. The Act specifically removed certain clinical decision support software (CDS) from the definition of a medical device—and therefore from the FDA's authority—as long as the CDS does not:

acquire, process, or analyze a medical image or signal from an in vitro diagnostic device, or a pattern or signal from a signal acquisition system for the purpose of—(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines); (ii) *supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition*; and (iii) *enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any such recommendation to make a clinical diagnosis or treatment decision regarding an individual patient.*²

Although the Act excludes certain CDS from the definition of medical device, the Act specifically grants the FDA discretion to determine that a technology is a device if the Department of Health and Human Services Secretary makes a finding that the software function would be reasonably likely to have serious adverse health consequences, and the software function has been identified in a final order issued by the Secretary after considering: “(i) the likelihood and severity of patient harm if the software function were not to perform as intended; (ii) the extent to which the software function is intended to support the clinical judgment of a health care professional; (iii) whether there is a reasonable opportunity for a health care professional to review the basis of the information or treatment recommendation provided by the software function; and (iv) the intended user and user environment”³

AI that does not explain how input data is analyzed or otherwise “show its work” clearly requires FDA regulation, as it does not allow for the independent review of the basis for such recommendations, and a false diagnosis could be deadly. A black box algorithm would fall into this category. Software that allows the independent review of the basis for the recommendation may or may not be subject to FDA regulation depending on

AI means different things to different stakeholders, but it is generally and broadly defined as computer engineering that results in the imitation of intelligent behavior or human learning and reasoning.

the Secretary's weighing of the four aforementioned variables. Of course, the FDA retains enforcement discretion. Assuming the software produces a diagnosis, and a provider relies on that diagnosis without the ability to question or review it, the software would clearly be subject to FDA regulation. The challenge that presents is how the FDA should regulate a device that learns and that is continuously and constantly evolving. That is the underlying difficulty in regulating a ML or deep learning modality. For example, the device may not be the same thing now that it was five minutes ago because during the intervening time, it has continued to obtain new information, adapted to that information for subsequent purposes, and improved its techniques.

There are other overarching challenges as well. Imagine, for instance, a virtual personal assistant providing a turnkey experience in managing your health care. It does not take much imagination to envision a voice-activated smart device having the ability to monitor the user's health vitals and to automatically schedule a doctor's appointment—at a time that is convenient with other scheduled priorities—based on the urgency of the perceived risk. The smart device could also track and schedule routine checkups, vaccines, and tests; reorder prescriptions; and notify emergency contacts when something is amiss. The smart device could also tell your self-driving car to fully take over if your blood pressure or blood sugar drops or spikes, and the smart device could be programmed to automatically send all results to your physician. For routine checkups, you may not even need to leave work or home, as your smart device could double as a telemedicine platform, taking your blood pressure, analyzing blood oxygen, and running other assessments of vital signs, all while you interface in real-time with your provider. AI can also help your doctor make sense of decades worth of electronic health data, identifying seemingly unrelated symptoms and ailments and identifying trends in laboratory results and clinical assessments that assist your provider in accurately diagnosing and prescribing a customized treatment based on your unique clinical history and physiology. Any prescriptions could be at your front door before you are home from work, and dosing reminders are automatically populated in your smart device, which will schedule a follow-up visit if your symptoms do not improve. Although this was a seemingly fantastical notion ten years ago, this possibility is on our horizon, and every single step poses a challenge in

today's regulatory framework. Existing laws and regulations will need to be overhauled, while new laws and regulations will need to be crafted to reflect our new AI-driven reality. The FDA is working to make this happen.

FDA's Consideration of Total Product Lifecycle-Based Framework

The FDA already has processes through which it reviews new medical devices, including 510(k) notification, de novo, or the premarket approval application. As a brief background, the 510(k) process arises when a manufacturer brings to market a moderate-risk device substantially equivalent to a device that has already been approved by the FDA. The FDA de novo process is reserved for low- or moderate-risk devices with no substantially equivalent device on the market, and the premarket approval process is meant for high-risk devices requiring demonstrated safety effectiveness before the FDA issues its approval.

The FDA has guidance to assist manufacturers in the decision whether to seek authorization to market a software change to a previously approved medical device. Generally, the FDA considers the 510(k) pathway to be potentially appropriate for software changes to a previously approved device, depending on the outcome of a risk-based flowchart provided by FDA.⁴ Modifications to previously approved 510(k) devices that may require subsequent premarket submission include changes that introduce a new risk or modify an existing risk that could result in significant harm, a change to risk controls to prevent significant harm, and a change that significantly affects clinical functionality or performance.

Acknowledging that the existing framework does not accommodate a device that changes quickly and in real time, as an AI device does, the FDA is exploring a total product lifecycle approach for AI and ML technologies. In April 2019, the FDA published a paper entitled *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)—Based Software as a Medical Device (SaMD)* that lays out the framework the FDA is considering (FDA Paper). The FDA Paper proposes a framework based on the International Medical Device Regulators Forum (IMDRF) risk categorization principles, the FDA's benefit-risk framework and risk management principles in the software modification guidance, and the organization-based total product life cycle approach envisioned in the Digital Health Software Precertification Program.

In conjunction with the FDA Paper, the FDA Commissioner released a statement promoting the FDA's commitment to applying "current authorities in new ways to keep up with the rapid pace of innovation and ensure the safety of [artificial intelligence] devices."⁵ The Commissioner noted that devices with AI capabilities that have been approved to date were limited to "locked" algorithms or reactive machines that do not continually update and improve and acknowledged the need for a framework that would allow for modifications to be made to algorithms from real-world learning and adaptation while ensuring safety.

The challenge that presents is how the FDA should regulate a device that learns and that is continuously and constantly evolving.

Risk Categorization

The framework proposed in the FDA Paper evokes the IMDRF risk categorization framework but does not explain how it would be applied. The IMDRF risk categorization framework examines the significance of the information provided by software and the state of the health care situation or condition. The significance of the information pertains to the intended use of the information provided to treat or diagnose and inform clinical management. The state of the health care condition relates to the seriousness of the disease or condition. Together these two factors can categorize the software from low to high risk. For example, if the software is only being used to inform clinical management (as opposed to diagnosing), and the health care condition is non-serious, the risk classification would be low. On the other hand, if the software is being relied upon to diagnose a patient, and the patient has a critical health condition, then the risk would be very high. The FDA Paper does not address how the risk classification will direct the review. Presumably, the higher the risk classification, the greater the scrutiny to be provided.

The FDA assumes that most software modifications to existing, approved medical devices will involve changes to coding and programming that result in different decision matrices and retraining existing algorithms with new data sets, which would be subject to premarket review. The FDA contemplates three categories of changes: performance, input, and intended use. The performance category includes modifications related to performance with no change to the intended use or new input type. The inputs category contemplates changes to the inputs used by the algorithm and their clinical association to the SaMD output. Modifications related to intended use include those that result in a change in significance of information provided by the software. The FDA notes that changes may not be mutually exclusive, and that while many changes would be subject to premarket review, some modifications may not require such review. Although the FDA contemplates different categories of modifications, the FDA Paper fails to describe how different modification categories will be treated.

Pre-Certification

The FDA Paper contemplates a pre-certification process whereby a device manufacturer is pre-certified by the FDA to qualify for a more streamlined premarket review based upon meeting certain criteria and demonstrating a history of and commitment to quality, excellence, and safety.

The Software Pre-Cert Program is an existing voluntary FDA program through which FDA evaluates a device manufacturer's

“culture of quality and organizational excellence” to determine whether the organization has demonstrated its ability to “build, test, monitor and proactively maintain and improve the safety, efficacy, performance and security of their medical device software products, so that they meet or exceed existing FDA standards of safety and effectiveness.”⁶ This Program is being used for approval of electronic medical record systems. FDA’s approach in this regard is based on several principles: (1) establishing clear expectations on quality systems and good ML practices; (2) conducting premarket review for SaMD that requires premarket submission to demonstrate reasonable assurance of safety and effectiveness and establishes clear expectations for manufacturers; (3) expecting manufacturers to monitor the device and incorporate a risk management approach in development, validation, and execution of algorithm changes; and (4) enabling increased transparency to users and FDA using postmarket real-world performance reporting.⁷

With respect to the first principle, the FDA describes good ML practices as those akin to good software engineer practices or quality system practices, and notes the following considerations for SaMD:

- » Relevance of available data to the clinical problem and current clinical practice;
- » Data acquired in a consistent, clinically relevant, and generalizable manner;
- » Appropriate separation between training, tuning, and test datasets; and
- » Appropriate level of transparency of the output and the algorithm aimed at users.⁸

With respect to the second principle of premarket assurance of safety and effectiveness, the FDA proposes a “predetermined change control plan” that includes the types of anticipated modifications, which it places in two categories: SaMD Pre-Specifications (SPS) and Algorithm Change Protocol (ACP). SPS include modifications and changes to performance or inputs related to the intended use of the AI (i.e., what the manufacturer intends the algorithm to become as it learns). The ACP specifies the methods in place to control the risks of anticipated modifications.

The third principle calls for manufacturers to evaluate modifications to SaMD based on risks to patients. The software modifications guidance expects manufacturers to perform a risk assessment and evaluate whether the risks are reasonably mitigated, and then either submit a new 510(k) for premarket review or document the modification and analysis in the risk management and 510(k) files.

The final principle involves transparency about the device’s intended function and any associated modifications in furtherance of safety. Manufacturers would commit to transparency and real-world performance monitoring and provide periodic reports to the FDA on updates that were implemented as part of the approved SPS and ACP as well as performance metrics. The FDA notes that transparency may include providing updates to the FDA, device companies, collaborators, and the public. The

FDA suggests that manufacturers explore different mechanisms for being transparent, including email, letters, and software notifications, and consider the amount of information to provide. Real-world performance monitoring may be achieved through reports to the FDA, and reporting may depend on the device, number of modifications, and maturity of the algorithm.

The proposed framework outlined in the FDA Paper describes a predetermined change control plan in premarket submissions that includes types of anticipated modifications and the associated methodology to implement those changes. The approach requires a commitment from manufacturers on transparency and real-world performance. This framework would allow the FDA to oversee AI that is constantly evolving and improving in a safe and efficient manner. The FDA Paper sought feedback through June 3, 2019. No date has been announced for further steps by the FDA.

Digital Health Guidance Documents

In October 2019, the FDA released new guidance that reflects small changes to prior guidance and provides clarity on the FDA’s thought process with respect to SaMD. While the guidance does not alter the FDA’s prior positions, it provides a more detailed analysis of risk factors that FDA will use to determine whether AI-driven CDS is a device subject to FDA regulations. Specifically, the Clinical Decision Support Software—Draft Guidance for Industry and Food and Drug Administration Staff (Draft Guidance) distinguishes software functions as either “Device CDS” or “Non-Device CDS” based on certain criteria. CDS that permits a health care provider to independently review the basis of the output recommended by the CDS and also meets the criteria of Section 520(o)(1)(E) of the Federal Food, Drug, and Cosmetic Act will be considered a “Non-Device CDS,” and in most cases either will be not subject to FDA regulatory oversight or not subject to enforcement at this time. The Draft Guidance also provides that, currently, certain Device CDS also will not be subject to enforcement.⁹ The determination of whether something is subject to regulatory enforcement, as described in the Draft Guidance, depends on whether it is intended to be used by a health care provider or by a patient/caregiver, whether the health care provider can independently review the conclusion or recommendation of the CDS, and if not, whether the condition or circumstances being evaluated by the CDS is significantly serious. The Draft Guidance included the helpful table (located on the following page):

When the FDA finalizes its regulatory approach, stakeholders will be able to more easily identify and resolve challenges and share the benefits of AI with health care providers and consumers.

Summary of Regulatory Policy for CDS Software Functions			
		Intended User Is Health Care Practitioner	Intended User Is Patient or Caregiver
IMDRF Risk Categorization	Can the User Independent Review the Basis?	FDA Regulation	FDA Regulation
Inform X Critical	Yes	Not a Device	Not a Device
	No	Oversight Focus	Oversight Focus
Inform X Serious	Yes	Not a Device	Oversight Focus
	No	Oversight Focus	Oversight Focus
Inform X Non-Serious	Yes	Not a Device	Enforcement Discretion**
	No	Enforcement Discretion**	Oversight Focus

**“Enforcement Discretion” indicates that, based on its current understanding of the risks of these devices, FDA does not intend at this time to enforce compliance with applicable device requirements.

The Draft Guidance was open for comment through December 26, 2019.

Conclusion

The FDA’s proposed framework, while vague in some areas, reflects a predetermined control plan in premarket submissions that would offer manufacturers of medical devices with AI capabilities a more flexible and practical approach for complying with FDA approval. The plan would require manufactures to describe anticipated modifications and the methodology for implementing them in a controlled manner that manages risk. The approach would also require manufacturers to commit to transparency, reporting, and real-world monitoring. When the FDA finalizes its regulatory approach, stakeholders will be able to more easily identify and resolve challenges and share the benefits of AI with health care providers and consumers. 

Any views and opinions expressed in this article are those of the authors alone and should not be attributed to AHLA.



Carolyn V. Metnick is a Partner at McDermott Will & Emery LLP in the firm’s Chicago office. She focuses her practice on health information privacy and security. She helps covered entities and business associates develop effective policies, procedures, and workforce training to comply with HIPAA and the HITECH Act. She

also counsels businesses in data breach investigations and compliance with other federal and state breach notification laws, and assists businesses in responding to cyberattacks and other security breaches. Carolyn also advises health care providers on transactions and business issues. She guides clients through joint ventures, mergers and acquisitions, and counsels on governance matters as well as regulatory issues. She advises on compliance with the federal fraud and abuse laws, including the Stark Law and the Anti-Kickback Statute. Carolyn’s background as a former litigator helps inform her transactional work.



Dina B. Ross is the sole proprietor of Dina B. Ross Law Offices. She focuses her practice on advising and assisting clients in meeting their technology legal needs in a variety of industries, including health care. She is experienced in drafting and negotiating commercial technology agreements in both established and emerging technologies, for both established and emerging companies. Ms. Ross also assists clients in navigating the technology legal issues during mergers, acquisitions, divestitures and other corporate restructurings with a particular emphasis in helping clients negotiate transition services agreements.

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Endnotes

- 1 See INTERNATIONAL MED. DEVICE REGULATORS FORUM (IMDRF), Software as a Medical Device (SaMD): Key Definitions (Dec. 2013), <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf>.
- 2 Section 3060(a) of the 21st Century Cures Act, Pub. L. No. 114-255 (emphasis added).
- 3 *Id.*
- 4 See FOOD AND DRUG ADMIN. (FDA), Deciding When to Submit a 510(k) for a Software Change to an Existing Device, <https://www.fda.gov/media/99785/download>.
- 5 FDA Statement, April 2, 2019.
- 6 Developing a Software Precertification Program: A Working Model, v1.0—January 2019.
- 7 Proposed Regulatory Framework for Modifications to Artificial Intelligence/ Machine Learning Based Software as Medical Device.
- 8 *Id.*
- 9 The Draft Guidance proposes that certain Device CDS would not be subject to enforcement of regulatory compliance at the current time, based on the FDA’s understanding of the risks of such Device CDS. For example, software intended to “inform clinical management” for non-serious conditions, such as a Device CDS that provides a health care provider with options for different diagnoses (e.g., seasonal allergic rhinitis versus common cold) would not be subject to enforcement currently.

For upcoming webinars on AI and information about the AHLA Convener on AI and Health Law, please see the inside back cover of this issue.

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More Data Please!

The Challenges of Applying Health Information Privacy Laws to the Development of Artificial Intelligence

By Adam H. Greene, Davis Wright Tremaine LLP

Artificial intelligence (AI)¹ has become part of our daily lives, from greeting us in the morning through smart home devices, creating shopping lists, playing music, setting timers, and alerting us of a traffic jam on our expected route home. AI offers substantial potential benefits for health care. AI can assist individuals with identifying whether a problem merits a trip to the doctor. It can watch an ill newborn and alert parents and doctors of signs of distress. AI can analyze huge datasets and identify patterns that otherwise may go unnoticed, such as unexpected side effects of drugs or contributing factors to improved outcomes.

The challenge is that AI will not improve health care in a vacuum. AI developers need tremendous amounts of health information to teach AI the vocabulary and grammar of medicine and the structure and meaning of electronic health record (EHR) and claims data. Generally speaking, the more data, the better the results.

AI's hunger for data, however, can create challenges under existing privacy laws. Federal and state legislatures and agencies did not draft current health information privacy laws, such as the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule,² with AI in mind. As a result, we are left applying old law to new technology—not a new or unique problem, particularly in health care, but always a challenge.

Attorneys counseling clients with AI-related health care activities may wish to consider:

- » Is de-identified information feasible;
- » Does AI “use” health information;
- » Is there a permissible purpose for the AI activity;
- » How does the Privacy Rule’s “minimum necessary” standard apply;

- » What is the impact of laws placing greater restrictions on information about certain sensitive conditions; and
- » Is notice, consent, and/or opt-out legally required or advisable?

This article focuses on privacy issues concerning protected health information (PHI). Attorneys also should consider various other legal issues related to AI, such as addressing potential inherent biases,³ and challenges with validating and explaining AI.⁴

Can the AI Developer Use De-Identified Data?

A threshold question is whether parties can perform an AI activity using de-identified data. HIPAA provides two means of de-identification:

- (1) The “Safe Harbor” method, in which the covered entity or business associate removes 18 categories of identifiers and does not have actual knowledge that the remaining information can identify an individual;⁵ or
- (2) The “Expert Determination” method, in which a covered entity or business associate obtains a written determination from an appropriate statistical expert that the risk of identification of an individual is very small.⁶

Many reasons exist to use de-identified data, where feasible. First, under the Privacy Rule’s “minimum necessary” standard, a covered entity or business associate must make reasonable efforts to use or disclose only the minimum necessary amount of PHI for an intended purpose, such as the AI activity.⁷ Accordingly, the AI activity should use de-identified information when it is feasible to do so. Second, once the information is de-identified, HIPAA will not apply. This would give the parties involved in the AI activity the most flexibility. For example, the Privacy Rule’s prohibition on the sale of PHI is not applicable to de-identified information, allowing a covered entity or business associate to receive remuneration in exchange for disclosing the data to an AI developer. Third, de-identifying the data best protects the privacy interests of the individuals, reducing privacy concerns and risk should a breach of the data occur.

Numerous challenges with de-identification, however, often make it infeasible. For unstructured data, a covered entity or business associate may find it difficult to ensure that they remove all of the 18 categories of identifiers. Attempting to de-identify this type of information through automation may lead to imperfect results and hiring persons to do so is time consuming and costly (and also likely to lead to imperfect results). Alternatively, hiring a de-identification expert involves the cost of the engagement, delay in engaging the expert (as they are in short supply), and delay in the expert reviewing the data and rendering a decision.

Additionally, de-identification under HIPAA does not necessarily constitute de-identification under other laws, such as the California Consumer Privacy Act or the European Union’s General Data Protection Regulation.⁸

AI developers need tremendous amounts of health information to teach AI the vocabulary and grammar of medicine and the structure and meaning of electronic health record (EHR) and claims data.

Is AI Processing a “Use” of Protected Health Information?

Another threshold question is whether AI’s processing of PHI even qualifies as a “use” or “disclosure” of PHI. In the Privacy Rule’s commentary, the Department of Health and Human Services (HHS) advised that “computer processing” of data does not constitute a “use” that is subject to the Privacy Rule:

Comment: One commenter observed that the definition [of “use”] could encompass the processing of data by computers to execute queries. It was argued that this would be highly problematic because computers are routinely used to identify subsets of data sets. It was explained that in performing this function, computers examine each record in the data set and return only those records in the data set that meet specific criteria. Consequently, a human being will see only the subset of data that the computer returns. Thus, the commenter stated that it is only this subset that could be used or disclosed.

Response: We interpret “use” to mean only the uses of the product of the computer processing, not the internal computer processing that generates the product.⁹

Based on this commentary, one reasonably can argue that an algorithm combing through terabytes of EHR data to “learn” does not constitute a “use” of the data for purposes of the Privacy Rule if no human ever lays eyes on the PHI.

There are reasons to be cautious with this position, however. The commentary is guidance, which does not have the force of law, and HHS may have changed its interpretation since December 2000 in light of significant technological advances. Additionally, HHS guidance regarding ransomware provides that computer processing (the action of an outside party’s malware accessing and encrypting data) constitutes a “disclosure” of PHI.¹⁰ If malware encrypting PHI without a human seeing the results is a “disclosure,” then HHS could interpret that AI processing the PHI without a human viewing the information is a “use.” This may indicate that HHS departed from its prior position and likewise considers internal computer processing of

A threshold question is whether parties can perform an AI activity using de-identified data.

PHI to be a “use” of the information. Furthermore, a regulator or court could distinguish between search queries—which do not identify data that do not meet search parameters—and AI, which arguably is using all of the data to “learn.”

Although the argument that AI’s analysis of PHI is not a “use” may prove helpful, the remainder of this article will take the conservative approach and treat AI’s application of algorithms to PHI as a “use” of PHI that requires a permission under HIPAA.

What Is the AI Activity’s Purpose?

When parties must use or disclose PHI for the AI activity, they should identify the purpose of the activity. This will dictate the application of HIPAA. An entity subject to HIPAA may not use or disclose PHI unless specifically permitted or required by HIPAA.¹¹

Treatment

One potential purpose is treatment. An example would be a HIPAA-covered health care provider using AI to assist with determining the best course of treatment for a patient. HIPAA would permit this activity as a use of PHI for the covered entity’s treatment purposes without an individual authorization.¹²

To qualify as “treatment,” the activity must involve a health care provider¹³ and be on behalf of a single individual, rather than a population.¹⁴ For example, the use of AI to review a population and identify patients who would benefit from an alternative treatment is a population-level activity and, therefore, qualifies as “health care operations” (discussed below) rather than “treatment.”¹⁵

Although HIPAA provides great latitude for uses and disclosures for treatment, a covered entity likely would need a HIPAA-compliant business associate agreement (BAA) with the AI vendor.¹⁶ Although HIPAA carves out treatment disclosures in the definition of “business associate,” this exception is limited to disclosures to health care providers.¹⁷ Unless the AI vendor qualifies as a “health care provider,” then the exception would not apply and HIPAA would require a BAA.

Payment

Another potential purpose of AI is payment. Examples would include a health care provider or its billing company using AI to identify an appropriate code for a health care service, or a health plan using AI to identify billed services that may be medically unnecessary. HIPAA would permit this activity as a use of PHI for the covered entity’s payment purposes.¹⁸ Again, HIPAA likely would require a compliant BAA with an AI vendor or an authorization

Health Care Operations

HIPAA also permits a covered entity or business associate to apply AI to PHI for a covered entity’s health care operations.¹⁹ HIPAA broadly defines “health care operations” to encompass a range of activities.²⁰ A covered entity or business associate could use AI technology to conduct almost any of these activities, from quality assessment and improvement activities, to planning where a health care provider should expand its footprint.

“Health care operations” are limited to “the activities of the covered entity to the extent that the activities are related to covered functions.”²¹ Although a business associate may use or disclose PHI to support a covered entity’s health care operations, HIPAA does not treat activities for the benefit of the business associate itself as “health care operations.” Additionally, the use of AI for purposes unrelated to “covered functions”—the functions that make an entity a health care provider, health plan, or health care clearinghouse—also would not be “health care operations.”²² For example, a health care provider using AI to improve sales at its gift shop seemingly does not relate to its covered functions and, therefore, arguably may not be “health care operations.”

“Health care operations” include the use of PHI to create de-identified data.²³ It does not matter how an entity then will use the de-identified information. For example, a covered entity’s use of PHI to create de-identified information that the covered entity will sell to an AI developer would constitute a health care operation. A business associate may use PHI to create de-identified information if permitted by the applicable BAA.²⁴ HHS has issued guidance permitting a business associate to de-identify information for its own benefit, rather than the benefit of the covered entity, if permitted by the BAA to do so.²⁵

Development of AI: Health Care Operations, Research, or None of the Above?

The million-dollar question—or maybe billion-dollar question—is whether development of AI could qualify as “health care operations” or “research.” The definition of “health care operations” includes “[c]onducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities.”²⁶ It also includes “population-based activities relating to improving health or reducing health care costs” and “protocol development.”²⁷

In contrast, HIPAA defines “research” as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”²⁸

If the purpose of developing AI is to use the AI to improve the quality of health care, evaluate outcomes, or develop clinical guidelines, then the activity may qualify as either health care operations or research. HHS has articulated that the line between the two is whether the “primary purpose” of the activity is to contribute to generalizable knowledge.²⁹

For example, if a health care provider engages with a company to develop AI primarily to improve the quality of health care for the health care provider’s patients, then the use and disclosure of PHI to develop the AI arguably is a health

care operation. The health care provider would need to enter into a BAA with the AI developer.

In contrast, if a health care provider engages with a company to develop AI primarily for purposes of contributing to generalizable knowledge, then the use and disclosure of PHI would be for research purposes. The activity generally would require: (1) the HIPAA-compliant authorizations of the patients; (2) an institutional review board or privacy board waiving the authorization requirement; or (3) the health care provider limiting the PHI to a limited data set and entering into a data use agreement with the AI developer.³⁰

HHS acknowledges that there may be circumstances where an activity begins as health care operations and then transitions to research.³¹ HHS directs that, in these cases, “the covered entity should document the change in status of the activity to establish that they did not violate the requirements of [the Privacy Rule].”³² Accordingly, if a partnership between a covered entity and AI developer begins primarily to improve outcomes for the covered entity’s population, but later transitions to primarily seeking to contribute to generalizable knowledge, then the parties should document the transition and begin to comply with the requirements for research.

There is little question that, if the parties’ primary purpose is to publish an academic paper regarding the effectiveness of the developed AI, then this qualifies as contributing to generalizable knowledge and, therefore, research. What if the parties develop the AI as part of commercial research and development? What if the parties do not intend to publish the result, but instead intend to sell the AI? This remains a gray area.

Contributing to generalizable knowledge arguably does not necessitate publication. For example, HHS commentary to the Privacy Rule references drug research of pharmaceutical companies—research that is commercial, rather than academic, in nature.³³ Although pharmaceutical companies are acting for commercial purposes, their research and development of new drugs arguably contributes to generalizable knowledge for purposes of HIPAA. Likewise, an AI developer’s research and development of AI to improve health care outcomes arguably contributes to generalizable knowledge and, therefore, would be research for HIPAA purposes. Calling the activity “research” is not a free pass under HIPAA. The parties generally would need to obtain an institutional review board or privacy board’s waiver of authorization, or limit the information to a limited data set, if they wish to conduct the activity without individuals’ authorizations.

Because the line between health care operations and research can get blurry, counsel should consider how the flow of payments between the parties and the ownership rights of intellectual property affect the perception of the primary purpose of each use and disclosure of PHI.

Applying the Minimum Necessary Standard

Generally, a covered entity or business associate must make reasonable efforts to limit the amount of PHI used, disclosed, or requested to the minimum necessary to accomplish the intended permissible purpose of the AI activity.³⁴ There is a natural friction between the Privacy Rule’s minimum necessary standard

The million-dollar question—or maybe billion-dollar question—is whether development of AI could qualify as “health care operations” or “research.”

and AI. Generally, the more data that AI receives, the better the AI will function. Accordingly, data scientists often will seek as much PHI as possible when developing AI algorithms.

The parties should consider what PHI really is necessary for the AI development and functioning. For example, assigning each individual a code that is not readily identifiable, rather than using a name or social security number, would promote compliance with the minimum necessary standard and would reduce the risks associated with the data set. Additionally, the parties should consider whether they could remove some fields of PHI as unnecessary.

In the end, the more PHI involved, the greater the risk under the minimum necessary standard. Accordingly, covered entities and business associates should consider documenting justification for why they deemed each data element necessary for the AI activity.

Consideration of Laws Other Than HIPAA

Of course, HIPAA is not the only game in town when it comes to privacy laws. 42 C.F.R. Part 2 governs records of federally-assisted substance use disorder (SUD) treatment programs. Most states have general privacy laws, which may be more stringent than HIPAA and, therefore, applicable. Additionally, states have laws governing certain sensitive conditions and treatments, such as HIV status, substance use disorders, mental health services, and genetic information. These laws may require consents or authorizations when HIPAA does not. Accordingly, parties involved in AI activities should consider whether to exclude certain information, such as SUD information.

As with de-identification, excluding sensitive conditions is sometimes an imperfect science. The parties should consider the level of risk and the allocation of risk (such as through indemnification provisions) should information about sensitive conditions impermissibly slip into the AI activity.

Other Privacy and Reputational Considerations

Finally, when considering applying AI to PHI, parties should weigh risks beyond legal compliance. For example, a partnership related to the use of PHI to develop AI generated widespread headlines and regulatory scrutiny in 2019.³⁵ The article that first publicized the partnership focused on the lack of patient consent and transparency. Yet the partnership may have fully complied with all applicable privacy laws without consent or transparency.

There is a natural friction between the Privacy Rule's minimum necessary standard and AI.

Sometimes, it is easy to fall into the trap of focusing exclusively on whether an AI activity is legally permissible. The parties also should consider the risks, including litigation and regulatory investigations, should a use or disclosure of health information for AI purposes end up on the front page of the newspaper. Although notice or consent for a specific AI activity may not be legally required, they nevertheless may be prudent means of reducing both legal and reputational risks. Accordingly, the parties should weigh the potential benefits against the burden and feasibility.

In conclusion, AI has great potential to improve health care. Covered entities can navigate privacy laws to use their health information to help achieve AI's potential in the health care sector. Compliance will not happen by accident, however, and will require careful forethought. **C**

Any views and opinions expressed in this article are those of the author alone and should not be attributed to AHLA.



Adam H. Greene is a partner in Davis Wright Tremaine LLP's Washington, DC office, where he primarily counsels health care systems, technology companies, and financial institutions on compliance with federal and state health information privacy, security, and breach notification laws. Adam is a former regulator at the U.S. Department of Health and Human Services, where he was responsible for determining how HIPAA rules apply to new and emerging health information technologies and where he was instrumental in the development of the current enforcement process.

Endnotes

- 1 For purposes of this article, we use the term "AI" to encompass a suite of related technologies, including artificial intelligence, machine learning, neural networks, and deep learning. Despite the distinctions between these different technologies, we believe they raise similar legal issues with respect to privacy laws.
- 2 Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. pts. 160 and pt. 164, subpts. A and E.
- 3 Ziad Obermeyer et al., *Dissecting racial bias in an algorithm used to manage the health of populations*, 6464 SCIENCE 447 (2019), <https://science.sciencemag.org/content/366/6464/447>.
- 4 Ariel Bleicher, *Demystifying the Black Box That Is AI*, SCIENTIFIC AM. (2017), <https://www.scientificamerican.com/article/demystifying-the-black-box-that-is-ai/>.
- 5 45 C.F.R. § 164.514(b)(2)(ii) (2019); see also U.S. DEP'T OF HEALTH AND HUMAN SERVS. (HHS) OFFICE FOR CIVIL RIGHTS (OCR), *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*, <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html> (last visited Dec. 6, 2019) [hereafter *OCR De-identification Guidance*].
- 6 45 C.F.R. § 164.514(b)(2)(i); see also *OCR De-identification Guidance*, *supra* note 5.
- 7 45 C.F.R. § 164.502(b) (2019).
- 8 CAL. CIV. CODE § 1798.140 (2019) (which requires certain safeguards against re-identification and that the data cannot reasonably be "linked" or "associated" with the individual, rather than only focusing on identifiability); Opinion 05/2014 on Anonymisation Techniques, Article 29 Working Party (2014), page 8, https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2014/wp216_en.pdf (de-identified information typically qualifies as "pseudonymized data," which is specifically included in the GDPR's definition of personal data).
- 9 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462, 82629 (Dec. 28, 2000) [hereinafter *Privacy Rule*].
- 10 OCR, Fact Sheet, *Ransomware and HIPAA*, <https://www.hhs.gov/sites/default/files/RansomwareFactSheet.pdf> (last visited Dec. 6, 2019).
- 11 45 C.F.R. § 164.502(a) (2019).
- 12 45 C.F.R. §§ 164.502(a)(1)(ii) and 164.506(a) and (c)(1) (2019).
- 13 45 C.F.R. § 164.501 (2019) (definition of "treatment"); *Privacy Rule*, *supra* note 9 at 82497-98 ("Activities are considered treatment only if delivered by a health care provider or a health care provider working with another party.").
- 14 *Privacy Rule*, *supra* note 9 at 82497 ("Treatment refers to activities undertaken on behalf of a single patient, not a population.").
- 15 *Id.* at 82626 ("While many activities beneficial to patients are offered to entire populations or involve examining health information about entire populations, treatment involves health services provided by a health care provider and tailored to the specific needs of an individual patient. Although a popu-
- lation-wide analysis or intervention may prompt a health care provider to offer specific treatment to an individual, we consider the population-based analyses to improve health care or reduce health care costs to be health care operations (see definition of 'health care operations,' above).").
- 16 45 C.F.R. §§ 164.308(b), 164.314(a), 164.502(e), and 164.504(e) (2019).
- 17 45 C.F.R. § 160.103 (2019) (definition of "business associate" at (4)(i)).
- 18 45 C.F.R. §§ 164.502(a)(1)(ii) and 164.506(a) and (c)(1) (2019).
- 19 *Id.*
- 20 45 C.F.R. § 164.501 (2019).
- 21 *Id.*
- 22 45 C.F.R. § 164.103 (2019) (definition of "covered functions").
- 23 45 C.F.R. § 164.501 (2019) (definition of "health care operations" at (6)(v)).
- 24 45 C.F.R. § 164.502(a)(3).
- 25 OCR, Frequently Asked Question #544, <https://www.hhs.gov/hipaa/for-professionals/faq/544/may-a-health-information-organization-de-identify-information/index.html> (Dec. 15, 2008); HHS NAT'L INSTS. OF HEALTH, *Health Services Research and the HIPAA Privacy Rule*, <https://privacyruleandresearch.nih.gov/healthservicesprivacy.asp> (May 20, 2005) ("a covered entity may provide a business associate that is also the de-identified data recipient with PHI, including identifiers, so that the business associate can de-identify the data for the covered entity.").
- 26 45 C.F.R. § 164.501 (definition of "health care operations").
- 27 *Id.*
- 28 45 C.F.R. § 164.501 (definition of "research").
- 29 *Privacy Rule*, *supra* note 9 at 82608 ("The distinction between health care operations and research rests on whether the primary purpose of the study is to produce 'generalizable knowledge.'").
- 30 45 C.F.R. §§ 164.508, 164.512(i), and 164.514(e). HIPAA also includes other permissions for research, such as review preparatory to research or research involving decedent information, but these are likely not applicable.
- 31 *Privacy Rule*, *supra* note 9 at 82608.
- 32 *Id.*
- 33 See, e.g., *Privacy Rule*, *supra* note 9 at 82652 ("In some cases, a covered entity could disclose protected health information to a pharmaceutical company for research purposes if the disclosure met the requirements of § 164.512(i).").
- 34 45 C.F.R. § 164.502(b).
- 35 Rob Copeland, *Google's 'Project Nightingale' Gathers Personal Health Data on Millions of Americans*, WALL ST. J., Nov. 11, 2019, <https://www.hhs.gov/hipaa/for-professionals/faq/544/may-a-health-information-organization-de-identify-information/index.html>.

Hot Topics on AHLA's Communities

Here's what people are talking about on the AHLA Communities. To view responses, add input, or post a question of your own, go to <http://communities.healthlawyers.org>.

Medical Staff, Credentialing, and Peer Review Topical Community

Does anyone have experience in establishing internal programs to address practitioners who exhibit behaviors that undermine a hospital's culture of safety? I would especially like to hear about efforts at early interventions that go beyond the collegial or "cup of coffee" conversations and even measures to address broader issues such as burnout or concerns with culture.

Health Insurance Topical Community

I'm working on an AHLA paper concerning provider liability to private payers for fraud and abuse. I'd appreciate your thoughts r.e. means private payers are currently using to combat fraud/abuse or obtain repayments from providers due to fraud/abuse, e.g.,

- 1.) Contract or provider manual terms that prohibit certain types of fraud/abuse (e.g., waiving copays, offering kickbacks, etc.), and/or require self-reporting and repayment of overpayments?
- 2.) 18 USC 1347 which prohibits fraud in health benefits programs?
- 3.) State laws that may affect fraud and abuse issues in private payor context?
- 4.) Common law tort or equity theories, e.g., fraud, misrepresentation, conversion, unjust enrichment, etc.?
- 5.) Others?

Governance Topical Community

Are any federal regulations triggered if a physician-owned practice requires maintaining a certain level of production as a requirement to be/stay a shareholder? The production level would be reasonable; it would require, at minimum, covering your own overhead plus a few percentage points.

Health Information Topical Community

Recently, I have encountered several vendors who would like to add limitation of liability language to our Business Associate Agreement form. In the past I have not agreed to any limitation of liability language in a Business Associate Agreement, but it seems to be a re-occurring issue. Does anyone have a solution or language that they could send me that may be agreeable to both a business associate and covered entity?

Fraud and Abuse Topical Community

EKRA has been with us for over a year now, and I am trying to get a handle on its impact.

As discussed by many, it has implications for what are customary activities in the clinical laboratory space—most significantly paying sales employees commissions based on the revenue generated from the business they bring in. While the AKS (covering federal health care program services) has the exception allowing bonafide employees to be paid commissions, EKRA does not. And while EKRA was intended to be addressing issues related to the opioid epidemic, as we know, its language is not drafted as narrowly as it should have been, such that its plain reading has it wiping out the bona fide employee exception under the AKS.

Has there been any information available regarding whether the government will be modifying EKRA or how they will enforce the EKRA requirements? And have labs been modifying their compensation programs for their employees to ensure they don't run afoul of EKRA, with its significant penalties?

Medical Frontiers in AI Liability

Danny Tobey and Allie Cohen, DLA Piper

In a world of interconnected, thinking machines, patients face new prospects for health and wellness, while providers have the blessing, and curse, of assistive and autonomous new tools for healing the sick. The blessing comes from above-human abilities to detect, diagnose, and treat. The curse comes from new forms of liability for health care providers, and a new set of concepts and cautions that didn't exist in the health care systems of the past.

This article analyzes some of the emerging liability issues at key points where systems interact and responsibilities are divided or unclear—at the margins of machine-provider, machine-patient, and machine-machine interactions. The analysis is not exhaustive (and how could it be given simultaneously evolving standards and concepts for Artificial Intelligence (AI) in health care?); rather, this article highlights some of the unifying concepts, concerns, and cautions the once and future health care provider should be thinking about while embracing these new and promising technologies.

Where Providers and Machines Meet: Who Decides and Who Overrides

What does the health care provider do, after years of academic and clinical training, when experience and insight say one thing and the machine-learning AI says another? Is the machine malfunctioning or is it seeing further? How is the doctor to know, and is she liable for overriding or not overriding?

Continuously learning, uninterpretable algorithms increasingly have the decisional autonomy—but neither the personal agency nor pass-through transparency—that make a legal system based on fault and deterrence an effective regulatory tool. Yet already they can outperform human doctors in several ways, and already doctors are hard pressed to detect false positives and negatives—overriding AI is more complicated than overriding a lab test that does not fit the totality of clinical data. And for those looking to sit out the scrum, there is another complexity—soon, with AI raising the achievable standard of care for patients, failure to adopt may provide new sources of liability.

Several agencies and associations are looking into these questions, attempting to provide frameworks in a rapidly changing environment. Among its numerous guidance documents on software issues following the enactment of the 21st Century Cures Act, the Food and Drug Administration (FDA) has proposed iterations of draft guidance to assess which clinical decision support software qualifies as a “device” and thus is subject to FDA’s oversight and regulation. Some of the FDA’s criteria may be relevant to providers and the assessment of their own liability in adopting these systems. A key aspect of FDA’s analysis begins with explainability—can a doctor independently review the basis for a machine’s recommendation? If so, this likely has implications for the distribution of liability as

well: if doctors can independently review the basis of the AI’s recommendation, responsibility more squarely rests upon them to make the final decision and exercise clinical judgment based on the totality of available data. But who assesses whether a doctor can “independently review the basis” for a machine’s recommendation? If, in defense of malpractice claims, doctors argue they could not, that issue may have to be litigated, to determine whether a physician of ordinary competence could have done so.

And what, exactly, does it mean to “independently review the basis” of an AI’s recommendation? Must the review include the same analysis the algorithm used? The language in FDA’s draft guidance, taken from the 21st Century Cures Act, suggests so, speaking of understanding “the” basis of a machine’s recommendation, not “a” basis or “any” basis that might support it.¹ Tracking the machine’s basis is often not possible—and yet physicians might be able to understand alternative or simpler explanations from the algorithm, allowing them to balance the machine’s “reasoning” against other clinical factors that might have been excluded. Would that process be enough to place responsibility on the health care provider? FDA further speaks of whether the AI is “intended” for health care professionals to rely on primarily, but liability may turn on reality of practice, not intention. Absent *a priori* standards, litigation of these issues will be fact-intensive and complex.

Meanwhile, developers and physicians still must grapple with the learned intermediary doctrine, which has the potential to protect an AI’s manufacturer from failure-to-warn claims for risks they have disclosed to intermediaries, like physicians. A successful learned intermediary defense by a manufacturer can turn into a medical malpractice case for a provider. What this means for providers is that adopting AI means understanding AI, enough to understand and explain its limitations. Some of these concepts will be familiar and portable from other diagnostic tools—standards of care; sensitivity and specificity (false positives and negatives, Area Under the Receiver Operating Characteristic curve). Others may not be: locked versus continuously learning algorithms; disparities between training data and local population data; levels of autonomous versus assistive guidance; algorithmic bias; and, eventually, general versus narrow AI. But, to avoid liability, providers must learn these concepts and, just as importantly, be able to explain them to their patients well enough to meet the duty of care.

More granular than the question of control is the look and feel at the very margins of human-machine interaction. The mechanics of “takeover” (as distinct from the *decision* to take over) is an additional pressure point in doctor-machine interactions. In robotic surgeries, the same code making recommendations to the human operator of a machine can also modify the tactile feedback received from the device: such attempts to



Designing these human-machine interactions means balancing risks, both AI and human, because neither is perfect.

see what people cannot, and often earlier. It never gets tired or bleary at the end of a shift. And yet its mistakes are at scale and often are harder to prove or explain. Careful balancing, thought on the front end, AI literacy, and documented procedures and policies are key. So are AI-specific, rather than boilerplate, terms of service, limitations of liability, representations and warranties, and other negotiated clauses that provide clear risk and responsibility allocation on the front end.

Where Patients and Machines Meet: AI-Telemedicine and the Doctor as Retrospectroscope

Telemedicine commonly follows the standard provider-patient model but uses the internet instead of the office as the site of connection. While remote visits are a huge step forward in expanding access to care, provider availability is still a limiting factor. For that reason, automated telemedicine—which allows more patients to interface directly with medical AI to receive diagnoses, prescriptions, and follow-ups—can be quite attractive. Indeed, patient-machine interfacing is already a part of the menu of telemedicine arrangements. Some services allow patients to get prescriptions online and don't involve physicians until after an algorithm recommends a drug. The efficiency is undeniable—but so is the potential liability. When a physician doesn't interact with the patient until *after* a prescription is written, what does that mean for informed consent and the learned intermediary doctrine? How much should the physician backstop the algorithm, and how much can she do so before the efficiency is lost?

Automated telemedicine brings a new and challenging possibility of mass informed-consent liability. In some instances of the current online prescription model, the only information physicians receive before writing a prescription is (1) a standard form filled out by the patient and (2) a recommendation from an algorithm.⁷ The patient is not necessarily counseled on treatment options and may have no opportunity to ask questions before being told what to take. The patient almost invariably consents to treatment, but the “informed” piece hangs in the balance.

Informed consent is a kind of medical malpractice liability. Under this doctrine, providers must give their patients enough information to allow them to make an intelligent decision.⁸ But with automated telemedicine, treatment plans may be presented in absolutes without a discussion of options or pros and cons—leaving the physician to provide this information. To avoid liability, providers should use their post-hoc patient interaction to explain (1) other available options and (2) their willingness to change the prescription (within medical reason). If patients know that their prescription is simply an option, providers are closer to knowing they have fulfilled their duty.

On the supplier side, automated telemedicine poses a greater risk. Life sciences companies may satisfy their common law duty to warn using the learned intermediary doctrine.⁹ The doctrine is predicated on the idea that providers are in a better position to warn patients of a product's dangers than manufacturers are. But when physicians don't interact with patients until *after* the prescription has been written, and then only through online messaging, physician warnings start to resemble labels, and the barrier of the “intermediary” thins.

Moreover, as AI systems evolve over the next decade, the question of who is the better informed intermediary—doctor or machine—will grow increasingly fraught. It is foreseeable that a judge may hold that the learned intermediary doctrine does not apply when patients are diagnosed and treated using automated telemedicine. FDA has noted that direct-to-patient AI will be an area of focus for its regulatory oversight not just when the software informs management of serious conditions, but when a patient cannot independently review a recommendation's basis for even non-serious conditions.¹⁰ Smart suppliers should be thinking about this now, designing systems and warnings that do not presume the learned intermediary doctrine will remain stable over time.

Where Machines Meet Each Other: Cyber-Physical Systems and Interoperability

The Internet of Things has become a familiar phrase for modern health care lawyers. Now, it's time to add cyber-physical systems (CPS) to the lexicon. CPS are interconnected networks of sensors and smart devices that monitor and interact with their environment. To illustrate, self-driving cars are CPS. They contain sensors that monitor their internal systems and the external environment, allowing them to react in real-time to both physical and digital data. That's why a smart car knows to brake differently when the car in front of it stops short on a sunny day versus a snowy day. Interconnected systems are already part of our health care system and daily lives, and we can expect continued advances in medical CPS (MCPS).

Systems that fall into this category can raise complex FDA regulatory questions, both in terms of the path to market, cybersecurity requirements in seeking FDA clearance or approval, and post-marketing obligations.¹¹ And once products have reached the market, it is not only FDA regulation in play. The Federal Trade Commission (FTC) may take action against companies marketing technologies purporting to offer medical, health, or performance-related benefits, applying high standards for substantiation of claims in these areas.¹²

MCPS are defined in part by interoperability—the ability of two or more software programs or devices to interface. Practitioners and developers alike need to understand the potential liability associated with interoperable devices and who is responsible when patients are harmed by faulty connections. The court in *Hansen v. Baxter Healthcare Corporation* placed the blame on developers, holding that the failing that caused a patient's death was a design defect,¹³ while other scenarios may place the duty on sophisticated health care systems to align their particular menu of IT offerings. The future of interoperability liability is an active subject of debate. In February 2019,

the Department of Health and Human Services announced a proposed rule¹⁴ that would expand the 21st Century Cures Act's ban on information blocking, clearing the path for growth of interoperable devices.¹⁵ Systems such as MCPS present a complex matrix of considerations for device safety and security, and developers should seek legal guidance early and often when adopting these systems.

Conclusion: Frontiers, Walls, and Bridges

The future of medicine is interconnection: machine-provider, machine-patient, and machine-machine. Managing the risks and rewards of these frontline interactions will be a moving target, but best practices are emerging. Seeing around corners is easier for those who keep abreast of cutting-edge developments at the intersection of science, technology, and law. Liabilities can arise anywhere, but these touchpoints *between* humans and machines are a key area where new frictions can be anticipated and managed. **C**

Any views and opinions expressed in this article are those of the authors alone and should not be attributed to AHLA.



Danny Tobey, MD JD, is a physician, successful software entrepreneur, and litigation Partner of DLA Piper, a global law firm in over 90 offices and 40 countries. Danny is a leader of the firm's global AI and data science team. He advised the AMA on its health care AI policies and was honored by the Library of Congress in 2019 for

his work on AI and the law. Danny has assisted leading life sciences and health care companies in matters involving FDA, CDC, CMS, HHS, private payors, and commercial litigants. He is a graduate of Harvard College, UT Southwestern Medical School, and Yale Law School, where he received the Gruter Prize for the best work on biological sciences and the law.



Allie Cohen, JD MBE, is a law clerk in DLA Piper's Product Liability group, working with clients in the health care and life sciences sectors. She has conducted research on developmental genetics in *Drosophila melanogaster* and has peer-reviewed publications in molecular biology and genetics. Allie graduated

from Cornell University as a Rawlings Cornell Presidential Research Scholar, with Honors in Biological Sciences. She received her J.D. from the University of Pennsylvania Carey Law School and her Master of Bioethics from the Perelman School of Medicine.

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[A]s AI systems evolve over the next decade, the question of who is the better informed intermediary—doctor or machine—will grow increasingly fraught.

Endnotes

- 1 H.R. 34, 114th Cong. (2016) (enacted); Clinical Decision Support Software 84 Fed. Reg. § 51167 (proposed Sept. 27, 2019). In other places, the language of the Cures Act suggests otherwise, explaining the "independent basis" standard as "so that it is not the intent that user rely primarily on any such recommendation." But that language blends the threshold prong of explainability with the separate prong of "degree of reliance" on the AI, which FDA raises later in its use of the International Medical Device Regulators Forum's risk matrix for enforcement discretion. An AI can be any combination of explainable/unexplainable and assistive/autonomous. The Cures Act's equating of these two independent factors may cause problems.
- 2 See, e.g., Fenton JJ, Taplin SH, Carney PA, Abraham L, Sickles EA, D'Orsi C, et al. *Influence of computer-aided detection on performance of screening mammography*, 356 NEW ENG. J. MED. 1399-409 (2007).
- 3 Clinical Decision Support Software 84 Fed. Reg. 51167 (proposed Sept. 27, 2019); see also FOOD AND DRUG ADMIN. GLOBAL APPROACH TO SOFTWARE AS A MEDICAL DEVICE (2017), <https://www.fda.gov/medical-devices/software-medical-device-samd/global-approach-software-medical-device-software-medical-device>.
- 4 AMERICAN MED. ASS'N, *Health care AI must boost the quadruple aim to move forward*, June 12, 2019, <https://www.ama-assn.org/practice-management/digital/health-care-ai-must-boost-quadruple-aim-move-forward>.
- 5 *Id.*
- 6 See Danny Tobey, *Software Malpractice in the Age of AI: A Guide for the Wary Tech Company*, Proceedings of the 2018 AAAI/ACM Conference on AI, Ethics, and Society, New Orleans, LA, USA—Feb. 02–03, 2018.
- 7 Yasmin Gagne & Burt Helm, *Buying prescription drugs online is easier than ever. But there are side effects*. FAST COMPANY (Sept. 11, 2019) (explaining "an algorithm analyzes patients' symptoms, then submits a diagnosis for a human doctor to review"), <https://www.fastcompany.com/90439144/machine-learning-could-transform-medicine-should-we-let-it>.
- 8 A successful informed consent claim requires (1) existence of material risk unknown to the patient, (2) failure to disclose the risk, (3) the patient would have made a different choice if the risk was disclosed, and (4) injury. *Canterbury v. Spence*, 464 F.2d 772, 786–87 (D.C. Cir. 1972).
- 9 *Ackermann v. Wyeth Pharmaceuticals*, 526 F.3d 203 (5th Cir. 2008).
- 10 Clinical Decision Support Software 84 Fed. Reg. 51167 (proposed Sept. 27, 2019) at 23.
- 11 See, e.g., FDA's October 2019 Urgent/11 Cybersecurity Vulnerabilities May Introduce Risks During Use of Certain Medical Devices, October 2018 draft guidance on Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, and December 2016 Postmarket Management of Cybersecurity in Medical Devices.
- 12 See, e.g., 80 Fed. Reg. 4575 (Jan. 28, 2015) (Focus Education, LLC, Analysis of Proposed Consent Agreement to Aid Public Comment); 80 Fed. Reg. 11437 (Mar. 3, 2015) (Health Discovery Corporation, Analysis of Proposed Consent Agreement to Aid Public Comment).
- 13 No. 89043, 2002 WL 93106 (Ill. Jan. 25, 2002). The providers settled.
- 14 84 Fed. Reg. 7424 (Mar. 4, 2019) proposed to be codified at 45 C.F.R. § 170-171.
- 15 Pub. L. No. 114-255 (2016). The comment period for the proposed rule is now closed, but will likely be finalized by 2022. Under the Medicare Modernization Act of 2003, Medicare final regulations have three years from a proposed or interim final rule to be published to the *Federal Register* as final rules.

Member News



Robinson+Cole has announced the promotion of **Nathaniel T. Arden** to counsel. Mr. Arden advises hospitals, health systems, physician groups, community providers, and other health care entities on a variety of health law and business issues. His practice focuses on health care-related regulatory and transactional matters, as well as health care-related information technology issues.



Norton Rose Fulbright LLP has announced the promotion of **Purvi Maniar** to partner. Ms. Maniar is a member of Norton Rose Fulbright's health care transactions team. Based in St. Louis and New York, she provides strategic advice to a wide range of clients

in the health care and technology industries in connection with their mergers, acquisitions, investments, joint ventures, and other strategic transactions.



Norton Rose Fulbright LLP has appointed partner **Stacey Murphy** as its Head of Health Care Practice in the United States. Murphy will steer the firm's U.S. health care strategy and oversee the firm's U.S. health care lawyers, who represent hospitals and health systems, academic medical centers, long-term care and assisted living facilities, retail pharmacies and wholesale distributors, multi-disciplinary physicians' groups, and health insurers.



Gary S. Sastow has announced that he has joined the health care industry group at Danziger & Markhoff LLP in White Plains, NY.

Firm News

Atlanta-based Chilivis Cochran Larkins & Bever is now Chilivis Grubman Dalbey & Warner. Chilivis Grubman will continue serving health care clients in all facets of criminal, civil, and administrative litigation. Chilivis Grubman partner **Scott Grubman** currently serves as the Vice Chair of Educational Programming for AHLA's Health Care Liability and Litigation Practice Group.

Whiteford Taylor & Preston LLP has announced that attorneys **Sigrid C. Haines** and **Roseanne M. Matricciani** are listed among the 2019 *Super Lawyers* and *Rising Stars* in Maryland.

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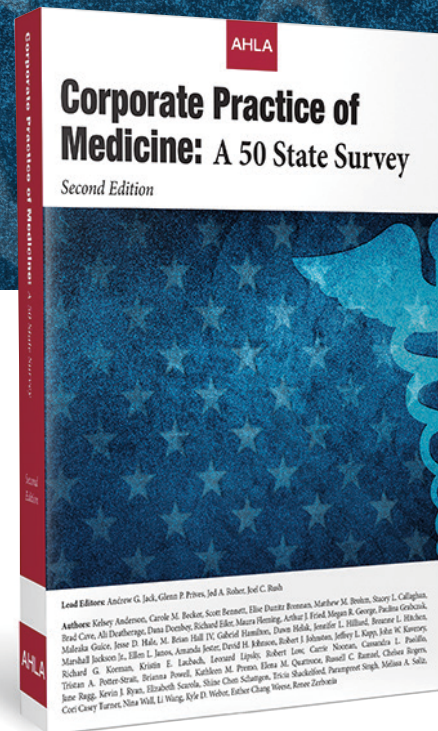
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Corporate Practice of Medicine: A 50 State Survey

SECOND EDITION

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The Importance of Female Mentorship in the Practice of Law

Julia E. Cassidy, Faegre Drinker Biddle & Reath LLP

You do not have to look very far to find an article or opinion piece on the challenges facing women in the professional workforce. Some of those challenges are unique to a particular profession—medicine, law, finance, business, etc.—while other challenges are shared by all women, regardless of the particular profession. The legal profession as a whole has made significant progress in its inclusion of women, as women now make up more than half of entering law school classes. There is still, however, a great deal of progress to be made in women progressing toward partnership and leadership positions in law firms. It is only recently that more and more firms have begun placing a great deal of emphasis on increasing efforts to promote more women to partnership and making attempts to retain higher numbers of female associates with the hope that such retention will lead in time to more female partners. With fewer female partners relative to male partners, one of the problems that can arise for younger, or less professionally experienced, women is a lack of female mentors. While by no means is it a requirement that a woman have female mentors, there are a number of factors that women may find beneficial in mentorship relationships with other women.

One of the benefits of women mentoring and supporting each other through their professional journeys is that there are issues that women will encounter throughout their careers that other women will understand and will have often experienced themselves, which men are unlikely to have faced. *The Harvard Business Review* recently published an article on ways to close the gender pay gap in the field of medicine, in which the author notes an example of differences between male and female physician experiences. In the article, the author noted that “further, research shows that patients tend to seek a different (and more time-consuming) kind of care from female doctors, often talking and disclosing more and expecting more empathic listening.”¹ This highlights an issue that female physicians may face in their professional lives, with which men are unfamiliar.

As women support and mentor one another, women can learn from the experiences that other women have already faced to better handle and overcome obstacles that come before them. Women may face any number of issues that men are less likely to face: not being taken seriously by firm staff or clients, an expectation that a woman should befriend staff members in order to avoid being seen as “bossy,” a hesitancy to take pride in accomplishments, and a greater reluctance to raise questions around salary and bonuses. When women encounter some of these challenges or have some of these concerns, the ability to

talk with another woman openly and seek her advice can not only be helpful, but also comforting in knowing that she is not the only person experiencing such issues. Additionally, many women face the challenge of maternity leave, and the potential effect such leave and subsequent change in schedule has on one's career path and trajectory, which men do not face. While firms and companies have made great progress in this arena with parental leave policies that are gender neutral, there is still progress to be made. The ability to talk to another woman who has had a child while at the same law firm or as an in-house counsel at the same company can prove to be extremely helpful and enlightening.

As women progress into more senior and prestigious roles in larger numbers, it is important that we support our more junior colleagues by actively trying to form mentorship relationships with other women who seek them. While attorneys are always busy with their day-to-day work and personal lives, if we take the time to talk to each other and learn from one another, we will collectively benefit from each other's experiences, as well as help the workplace continue to become a more inclusive and supportive environment.



Julia E. Cassidy is an associate in the Health Care Group of Faegre Drinker Biddle & Reath LLP in Florham Park, New Jersey. She represents hospitals, health care systems, and physician practices in all aspects of health care corporate, regulatory, and transactional matters. She advises clients in a variety of business transactions including mergers, acquisitions, and affiliations, as well as contractual matters such as professional service agreements, clinical integration networks, and health care entity corporate documents. Ms. Cassidy earned her JD from Case Western Reserve University School of Law and her BA from the University of Pennsylvania.

Endnotes

- 1 Rotenstein, Lisa S. and Dudley, Jessica (November 4, 2019), How to Close the Gender Pay Gap in U.S. Medicine, *The Harvard Law Review*, <https://hbr.org/2019/11/how-to-close-the-gender-pay-gap-in-u-s-medicine>

Embrace Your “Squiggly Line” Journey

Ashley Thomas, Morris Manning & Martin LLP

Last fall, a friend invited me to a book launch party for entrepreneur and motivational speaker Fallon Ukpe, MD, MBA, discussing her new book “Life Is a Squiggly Line: Start Embracing Imperfection and Stop Settling for Safe.” The title immediately had me hooked, and I was intrigued to learn more from Fallon. I was riveted by her discussion and devoured the book once I got home. What is meant by the title of the book—“life is a squiggly line”—is that life is not meant to be perfect; there are going to be ups and downs and various life transitions (sometimes unexpected). But in the end, it’s all going to work out if you take charge of the journey and focus on growing through those experiences. In the book, Fallon details how she made the tough decision to pursue a career in business instead of pursuing a residency after graduating from medical school. As her passions evolved, she gained a better understanding of her talents that lead to her decision to pursue a business career, and she never looked back. This book really resonated with me as I feel like my life has been a squiggly line since graduating from law school. I’ve worked in an in-house setting, and for multiple firms in different states, all the while volunteering with AHLA. Did I know that this is where my journey as a health care attorney would lead? No. But I’m glad that it has, and I’m grateful for this “squiggly line” journey of my own and what it has taught me. For the young professionals reading this article, this is what I’ve learned along the course of my squiggly line career.

Perfection Is Unattainable

We can all probably agree that we think of success as a straight-line trajectory that goes up and to the right. But the career paths to fulfillment and success are rarely linear. We expect perfection, but it’s impossible to achieve. Yet, we still strive for it, living our lives on a hamster wheel of sorts, as Fallon would say. Part of the squiggly line journey is embracing imperfection and accepting that there will be peaks and valleys in life. Life isn’t perfect, and your career path won’t be perfect either. We go through these ups and downs to help us become better versions of ourselves, which propels us to meaningful achievement. Embracing imperfection is difficult but worth the peace of mind.

Build on Failure

You’re going to make mistakes and fail along the way. James Dyson (whose name is now synonymous with the vacuum) spent 15 years creating 5,126 prototypes of the Dual Cyclone vacuum cleaner that eventually made him a billionaire. He initially struggled to sell his product to a manufacturer and admitted his success didn’t come overnight but through many years of trial and error and learning through his failures. As Henry Ford once said, “the only real mistake is the one from which we learn nothing.” In order to learn from those failures

and mistakes, it’s best to acknowledge and own the mistakes you make along the way. As lawyers, we try to convince our clients and colleagues that we understand the law. We also earn respect when we admit we’re wrong and own up to it. It can be hard to suppress the internal monologue that tells us we are going to be fired when we make a mistake. But it’s important to take a step back and ask ourselves how we can learn from that setback. We can treat it as a learning opportunity to talk with a partner, mentor, supervisor, or colleague and discuss how we can grow from that experience.

Go for It

In the fall of 2014, AHLA announced that it was accepting applications for the newly created Social Media Coordinator positions with AHLA’s various practice groups. I was interested in applying, but I had just graduated from law school that year and felt timid sending an application because I was a first-year attorney. I had been volunteering while in law school with AHLA’s social media program, but I was still apprehensive to apply. I talked with AHLA staff member Arnaud Gelb (who I miss dearly), and I voiced my concerns to him. I remember him saying “so what?” and that it wouldn’t hurt to apply. He reassured me that I was ahead of the curve on social media despite my lack of years of experience as an attorney. With his encouragement, I pushed myself outside of my comfort zone and applied for the Social Media Coordinator position with the Physician Organizations Practice Group. And I got it! That role opened doors for me by creating new opportunities within AHLA, from writing newsletter articles, working with and learning from a great leadership team within the Physician Organizations Practice Group, to a subsequent leadership role within the Public Health System Affinity Group. AHLA has been a constant source of support in my legal career, and I wouldn’t have come this far without that support. Through the educational resources, in-person programs, and writing and networking opportunities, AHLA has helped me learn and grow as an attorney. I’m thankful for the opportunities and connections I’ve made along the way. I’m glad that I pursued those opportunities.

My final advice to young professionals: embrace imperfection, build on failure, go for it, and enjoy the ride. This is how you can embrace your squiggly line journey.



Ashley Thomas, CIPP/US, CIPP/Es, is an associate attorney in the Washington, DC office of Morris Manning & Martin LLP. She currently serves as the Vice Chair of Publishing for AHLA’s Public Health System Affinity Group.

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Denver, CO: Director, Senior Corporate Counsel—DaVita. This attorney will provide legal guidance and support to the company on regulatory and compliance-related matters, including, but not limited to, federal and state fraud and abuse laws and other health care regulatory laws as such matters arise in the context of outpatient dialysis centers and related businesses. The attorney's primary focus will be supporting the company's transactional arrangements. This position requires expertise in federal health care regulatory laws, including the False Claims Act, the federal Physician Self-Referral Law (Stark Law), the Anti-Kickback Statute, the Civil Monetary Penalties and Beneficiary Inducement laws, and their implementing regulations. This attorney should also have expertise in contract drafting and negotiation with a preference for joint venture arrangements and M&A transactions. Minimum qualifications include a JD with a minimum of four years of legal practice in the health care industry. For immediate consideration email patricia.festa@davita.com.

Iowa

Des Moines, IA: Health Associate Attorney—Dorsey & Whitney LLP. Dorsey & Whitney LLP seeks a highly motivated health care associate with one to four years of experience to join a very busy practice in the health care group in our Des Moines office. The position will focus on transactions and regulatory compliance health care work (e.g., drafting and negotiating contracts, Medicare and Medicaid compliance advice, and HIPAA advice). Successful candidates will have one to four years of health law experience, superior academic credentials, and very strong communication, writing, research, and analytical skills. A background in the health care industry and Iowa bar admission is preferred. The candidate must have a strong knowledge base in the business and regulatory aspects of health law, including Stark, Anti-Kickback, licensing and nonprofit laws, and strong contract drafting skills. Dorsey & Whitney LLP is an EEO/AAP/Disabled Vets Employer. Apply online at www.dorsey.com/attorneyjobs.

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For more information and to start the journey to enhance your career or organization, please visit the AHLA Career Center at <https://careercenter.healthlawyers.org>.

New Website and Member Portal Coming Soon

AHLA will launch a new website and member portal next month. Based on previous focus group discussions, current data analytics, and regular feedback from our members, the new website and member portal are not just an update to existing infrastructure, but a migration to a new content management system with enhanced personalization and functionality aimed at ensuring you can quickly find the content you're looking for in fewer clicks.

Website

We are building on the Mega Menu launched last August and simplifying the menu structure. This will allow web visitors to quickly jump to various educational opportunities, browse the latest news and analysis from your Practice Groups, see the latest discussion threads from your Communities, and find publications and member resources with ease.

Additionally, because we know your Practice Group enrollments and content preferences, we are using this data to tailor and personalize your web experience. What does this mean? When you log in, your home page may look very different from that of your colleagues. You will have quick access to your Practice Groups, educational offerings and news and analysis will be tailored to your preferences (with options to see all content),

and publications and resources related to your interests will display for deeper dives into similar content.

Plus, we continue to improve search functionality. The new search offers a more robust set of filters while bringing the Health Law Archive into the same viewing pane, so those with subscriptions to the Archive can more easily search the main website and toggle over to the Archive without logging in again or entering the same search terms.

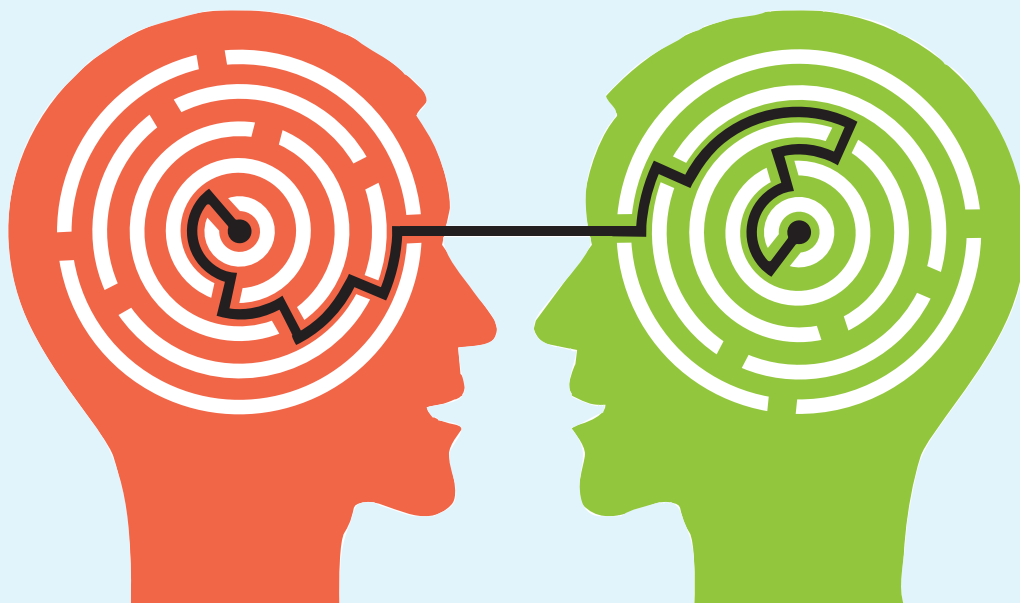
These streamlined search features should ensure you find what you're looking for in a shorter amount of time.

Member Portal

We are moving eCommerce, myAHLA pages (profile, transactions, preference and subscription center, downloads, etc.), and the AHLA Member Directory into a true member portal. At the same time, we're streamlining program registration, adding the ability to view/print receipts, reconfiguring the preference and subscription center, and so much more!

We are excited about harnessing the newest technology to better serve your growing online needs. If you have any questions or suggestions on how we can improve the member experience, please let us know at webmaster@healthlawyers.org.





AI and Health Law: Education and Dialogue

Artificial intelligence is poised to become a transformational force in health care. There are nearly endless opportunities to leverage technology to deploy more precise, efficient, and impactful interventions at exactly the right moment in a patient's care. Inevitably, health law will have to respond to these changes.

AHLA is positioned to provide the information and resources that members need for navigating the cutting-edge legal issues that AI poses for the health care industry.

Education

To further expand our educational offerings in this important area, mark your calendars for AHLA's four-part webinar series dedicated to key legal issues for AI in health care:

AI and Health Law: Overview—Myth Versus Reality—February 25

AI and Health Law: Payment and Coverage Issues—March 31

AI and Health Law: Liability Issues and Data Bias—April 28

AI and Health Law: Privacy and Security—May 19

The webinar series is free for AHLA members as a benefit of membership.

Dialogue

AHLA is hosting a day-long convener at the Microsoft Innovation & Policy Center in Washington, DC on March 10. This meeting will bring together more than a dozen thought leaders including regulators, clinicians, private practitioners, and other leading authorities for an in-depth discussion of AI in health care. Although AHLA conveners are closed to the public and press to ensure a full and open dialogue among invited stakeholders, the main perspectives and themes from the discussion will be summarized and consolidated into a white paper that will be distributed to convener attendees, AHLA leaders and members, and the public in early summer 2020.

To explore these and other AHLA publications and resources devoted to AI in health care, visit our new Hub page at www.healthlawyers.org/AI.

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