AHLA

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For the health and life sciences law community

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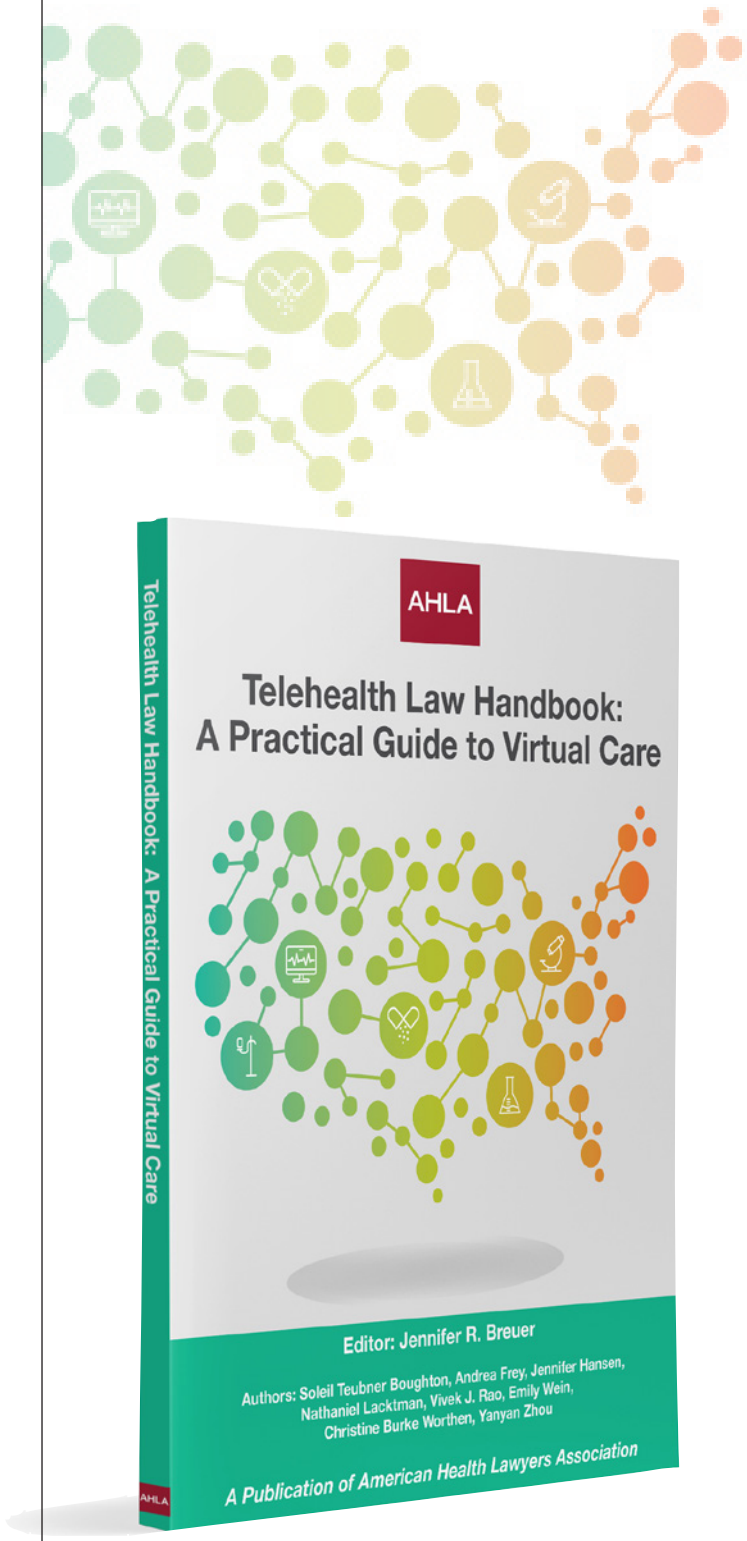
OFFICIAL MAGAZINE OF AMERICAN HEALTH LAWYERS ASSOCIATION



Telehealth Law Handbook: A Practical Guide to Virtual Care, Second Edition

Jennifer R. Breuer, Editor

Soleil Teubner Boughton, Andrea Frey, Jennifer Hansen, Nathaniel Lacktman, Vivek J. Rao, Emily Wein, Christine Burke Worthen, Yanyan Zhou, Authors

This new publication is an invaluable guide for attorneys, compliance officers, and providers looking to represent clients, manage risk, and address emerging issues in this area. Telehealth is becoming an integral part of the business plans of health care organizations across the country. While opportunities continue to grow, so do the attendant legal and regulatory issues.

THE LEGAL LANDSCAPE ACROSS JURISDICTIONS

In a highly state-dependent area of practice, you must be prepared to understand requirements in all 50 states. This new book will prove indispensable for this purpose.

COMPREHENSIVE AND IN-DEPTH COVERAGE

From licensure and regulatory requirements, to payment and ethical considerations, you'll find in-depth coverage from experts in this area. Look to the *Telehealth Law Handbook* for:

- Telemedicine licensure requirements in all 50 states including types of state licensure, exceptions, and how licensure laws apply in various practice situations
- The application of state regulations on the physician-patient relationship, validation of identity, informed consent, vulnerable populations, non-physician providers, remote prescribing, and continuity of care
- Payment and reimbursement rules under Medicare and Medicaid, telehealth commercial insurance, and a 50-state survey of state telehealth commercial insurance coverage laws
- Emerging legal and ethical issues, including medical staff credentialing, fraud and abuse compliance, corporate practice of medicine prohibitions, privacy and security, and mobile health technology

For more information go to:
www.healthlawyers.org/bookstore

So Many Ways to Get Involved

I believe that we are a collection of the choices we make. Each decision node we encounter, whether large (should I marry this person?) or small (do I want fries with that?), has repercussions and shapes who we are.

One of the best choices I made in life, and one that has profoundly shaped who I am as a professional and as a person, was my choice to get involved in AHLA. In 2001, I was asked by a colleague, who was a leader of a Practice Group, if I would be interested in participating in the Practice Group. To that point, I had been only a passive member, thoroughly enjoying the benefits of AHLA: receiving the *Health Law Digest* (it's not published any more) and attending in-person programs. Funny enough, when I sought advice from another colleague about whether to accept the invitation, I was discouraged. "It will take too much time," she warned. Boy, am I glad I didn't follow that advice! I accepted the invitation, and so began nearly 20 years of involvement—remarkable and rewarding involvement—with AHLA.

I would not be the lawyer I am today were it not for AHLA. This organization—the education it has provided, the relationships I have made, and the experiences I have had—have made me a better lawyer and have enriched me as a person. I could not possibly have imagined then what that one decision—that one choice—would lead to.

Now I invite you to get involved in AHLA. There are countless ways to do so, and getting involved is easy. AHLA has numerous opportunities for engagement. Some take a few hours a month, others require a bigger commitment of time, but all provide important help to the organization, benefits for your health law community, and valuable personal growth.

Each year, AHLA conducts a Call for Leaders in December and I thank those of you who applied for a position. Final decisions will be made in the Spring. If you are not selected, please remain involved.

No matter where you are in your career, no matter how long you have been an AHLA member, no matter whether you have served in a leadership role previously or not, there are many ways to get involved, and many needs within the organization.

There are plenty of opportunities for service. On the Volunteer webpage (https://www.healthlawyers.org/Volunteer) on the AHLA website, you will find plenty of ways to get your feet wet. You could serve as a mentor, live Tweet an upcoming program, or update a program, just to name a few.

It is easy to learn more about these opportunities and which one is right for you. If some activity catches your eye, reach out to another AHLA member who is already involved in that activity. I assure you they will be happy to tell you about their work and learn of your interest. AHLA's staff in the Membership and Practice Group Engagement Department can also answer your questions.

As President, one of my greatest privileges, and challenges, is appointing people to leadership positions. In most instances, we are blessed with lots of volunteers, and difficult choices among many talented individuals. Sometimes, however, we have to proactively find and invite someone to fill a leadership role because no one has volunteered.

Now is your chance to enhance your career and life. Maybe your choice to get involved will be an isolated experience full of mutual reward, but without a profound and lasting impact. But maybe, just maybe, your choice to get involved will trigger a journey that will one day have you also saying: "one of the best choices I made was my choice to get involved in AHLA."

Eric Zimmerman
President, FY18
ezimmerman@mwe.com

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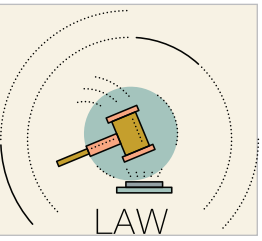

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- Population Health and Clinical Integration

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— Patrick Moore, Esq. / Patrick K. Moore Law Corporation / Irvine, CA

"I retained Dr. Jon Burroughs recently on a difficult and complex case. Jon thoroughly addressed the issues, provided fantastic insight and literature, and gave a spotless deposition! Highly recommended!"

— James Ball, Esq. / The Ball Law Group / Chicago, Illinois

"In addition to providing a thorough review and extraordinarily detailed report, Dr. Burroughs takes the time to break down difficult concepts in all aspects of hospital administration. Dr. Burroughs gives attorneys the tools necessary to present very strong system failure cases. He exceeds all expectations to include giving a rock solid deposition. I highly recommend Dr. Burroughs."

— Carol Hay, Esq. / Las Vegas, Nevada

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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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AHLA

The Collision of Fair Market Value and Commercial Reasonableness in Physician Compensation

Four-Part Series: December 6, 2017; January 17, February 7, and March 7, 2018 (2:00-3:30 PM Eastern)

In this four-part webinar series, AHLA's Fair Market Value Affinity Group of the Hospitals and Health Systems Practice Group will bring together top legal and valuation experts to discuss the collision between physician compensation arrangements, fair market value, commercial reasonableness, and process.

Part I: Fair Market Value and Commercial Reasonableness 101: Distinguishing Between Legal Requirements, Developing Best Practices and Dogma

Having a thorough understanding of the requirements of fair market value and commercial reasonableness is critical to maintaining compliance with applicable laws and regulations. This webinar will set the stage for our webinar series by bringing together legal and valuation experts to distinguish between what is legally required, what is a developing best practice and finally, to discuss common misunderstandings and misconceptions related to fair market value and commercial reasonableness in the industry.

Part II: Appropriate Oversight, Meddling or Both? Delving into the Expanding Role of Boards and Compensation Committees in Physician Compensation Governance

Oversight over physician compensation arrangements within a health care organization typically rests with the governing board and under many structures the oversight is delegated down to a compensation committee of the board. The oversight ultimately developed by a health care organization is often driven by corporate structure, risk tolerance or other factors. This webinar will explore the expanding role of boards and committees in physician compensation oversight, in decision-making and in day-to-day policy and process implementation. Our panel of experts will discuss emerging governance structures, reporting and documentation requirements, approval processes, and other developing best practices in the industry that can help appropriately engage the board and/or committee in oversight, while avoiding meddling.

Part III: Sharing the Load: Maximizing the Working Relationship Between Management, Finance, Legal, Compliance, Outside Counsel and Appraiser in the Physician Compensation Process

Compensation processes are only as strong as their implementation and recent enforcement actions have highlighted the dangers of establishing, but then failing to consistently follow a physician compensation process. This webinar will focus on the importance of developing a systematic compensation process that appropriately integrates legal, finance, compliance, management, and business line leaders to support informed decision-making. Our panelists will discuss emerging contracting processes, documentation guidelines, approval requirements, and other developing best practices that health care organizations may adopt to streamline their process.

Part IV: Right Sizing Your Fair Market Value and Commercial Reasonableness Process: Finding an Approach that Aligns with Industry Guidance and Developing Best Practices, and What Works for You

The government has noted in its guidelines on physician compensation that responsibility for determining fair market value ultimately rests with the parties to the arrangement and that health care organization must have in place processes for making and documenting reasonable, consistent and objective determinations of fair market value. In order to meet these obligations, health care organizations must develop a right-sized process that can be implemented effectively and consistently. This webinar will survey a continuum of approaches (both internal and external) for determining and documenting fair market value and commercial reasonableness.

Register Now! Online at: www.healthlawyers.org/webinars

Connections to Learning

February

5-7

Physicians and Hospitals Law Institute, Featuring a HIT Program Track

Sheraton New Orleans
New Orleans, LA

Platinum Sponsor: HORNE LLP
Gold Sponsor: PYA, Sullivan Cotter and Associates Inc
Silver Sponsor: HealthCare Appraisers Inc

- Feb 5–Antitrust, In-House Counsel, and Hospitals and Health Systems Practice Groups Joint Luncheon, *sponsored by ECG Management Consultants*
- Feb 5–Networking and Diversity+Inclusion Reception, *hosted by AHLA's Diversity+ Inclusion Council, sponsored by HORNE LLP*
- Feb 6–Networking Breakfast, *hosted by AHLA's Women's Leadership Council, sponsored by Pinnacle Healthcare Consulting*
- Feb 6–Physician Organizations Practice Group Luncheon
- Feb 6–Medical Staff, Credentialing, and Peer Review and Health Care Liability and Litigation Practice Groups Joint Luncheon, *sponsored by NorthGauge Healthcare Advisors LLC*
- Feb 7–Health Information and Technology Practice Group Luncheon, *sponsored by HORNE Cyber*

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Long Term Care and the Law

Sheraton New Orleans
New Orleans, LA

Principle Valuation LLC and PYA have provided sponsorship in support of this program.

- Feb 28–Networking and Diversity+ Inclusion Reception, *hosted by AHLA's Diversity+Inclusion Council, sponsored by Principle Valuation LLC and PYA*
- March 1–Post-Acute and Long Term Services Practice Group Luncheon, *sponsored by Simione Healthcare Consultants LLC*

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Free
In-Person Program, Training
Leadership Opportunity
Member Event
Networking, Reception
Registration Cost
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.

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Institute on Medicare and Medicaid Payment Issues

Baltimore Marriott Waterfront
Baltimore, MD

PYA has provided sponsorship in support of this program.

- Mar 21–Regulation, Accreditation, and Payment Practice Group Luncheon
- Mar 21–Networking and Diversity+Inclusion Reception, *hosted by AHLA's Diversity+Inclusion Council, sponsored by PYA*
- Mar 23–Networking Breakfast, *hosted by the Women's Leadership Council*

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Gaylord Opryland® Resort & Convention Center
Nashville, TN

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- May 10–Business Law and Governance Practice Group Luncheon
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Ritz-Carlton Pentagon City
Arlington, VA

Co-sponsored by AHLA, ABA Health Law Section, and ABA Section of Antitrust Law

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Annual Meeting

Hyatt Regency Chicago
Chicago, IL

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Volunteer Recognition: November 2017

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
Thomas R. Barker, Foley Hoag LLP
Annapoorani Bhat, PYA
Ritu Kaur Cooper, Hall Render Killian Heath & Lyman PC
Benjamin Martin Daniels, Fresenius Medical Care North America
James F. Flynn, Bricker & Eckler LLP
John B. Garver III, Robinson Bradshaw & Hinson PA
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Lisa Marie Gora, Wilentz Goldman & Spitzer PA
Scott R. Grubman, Chilivis Cochran Larkins & Bever LLP
Jeanna Palmer Gunville, Drinker Biddle & Reath LLP
Carla J. Hartley, Dillingham & Murphy LLP
Donn H. Herring, Lathrop & Gage LLP
Tizgel K. S. High, LifePoint Health
Lindsay P. Holmes, BakerHostetler
William E. Hopkins, Shackelford Bowen McKinley & Norton LLP
William W. Horton, Jones Walker LLP
Albert D. Hutzler IV, HealthCare Appraisers Inc
David E. Kopans, Jones Day
Marilyn Lamar, Liss & Lamar PC
Peter M. Leibold, Ascension Health
Kim Harvey Looney, Waller Lansden Dortch & Davis LLP
William Taylor McNeill, US Attorney's Office, Middle District of Georgia
Deanna S. Mool, Heyl Royster Voelker & Allen
Linda Sauser Moroney, Drinker Biddle & Reath LLP
Michael E. Paulhus, King & Spalding LLP
Robert A. Pelaia, University of South Florida
Karen S. Rieger, Crowe & Dunlevy PC
Craig H. Smith, Hogan Lovells LLP
Thomas Spellman, Fresenius Medical Care North America
Christine L. White, Northwell Health
Teresa A. Williams, Integris Health

Institute for Health Plan Counsel
Michael Apolskis, Health Care Service Corporation, Blue Cross and Blue Shield of Illinois
Ethan Baumfeld, Health Care Service Corporation, Blue Cross and Blue Shield of Illinois, Montana, New Mexico, Oklahoma and Texas
Lisa Campbell, The Groom Law Group
Theresa Claffey Carnegie, Mintz Levin Cohn Ferris Glovsky & Popeo PC
Nicole Cerquitella, Aetna Inc
Dorothy DeAngelis, Navigant Consulting Inc
Jeremy Earl, McDermott Will & Emery LLP
Jamshid Ebadi, Crowe Horwath LLP
Lauren N. Haley, Strategic Health Law
Anne W. Hance, Blue Cross Blue Shield of Tennessee
Denise Elizabeth Hanna, Locke Lord LLP
Lisa A. Hathaway, Aetna Inc
Garrett Heenan, Prescription Solutions a United Health Grp Co
Jonathan M. Herman, Herman Law Firm
Scott J. Heyman, Sidley Austin LLP
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Michael Strauss Kolber, Manatt Phelps & Phillips LLP
Marilyn Lamar, Liss & Lamar PC
Joseph Miller, Crowell & Moring LLP
Joel Mintzer, Blue Cross and Blue Shield of Minnesota
Eric B. Myers, BlueCross BlueShield of Tennessee Inc
C. Brooks Newman, Humana Inc
Thomas F. O'Neil III, Cigna Corporation
Kathryn A. Roe, The Health Law Consultancy
John B. Shely, Andrews Kurth LLP
Brian Richard Stimson, Office of the General Counsel, U.S. Department of Health and Human Services
Ursula Taylor, Butler Rubin Saltarelli & Boyd LLP
Bryan Webster, Reed Smith
Cynthia F. Wisner, Trinity Health
Jeff Joseph Wurzburg, DHHS Office of the General Counsel

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The Focus on Individuals in Fraud Investigations and Considerations for D&O Insurance
Danielle M. Corcione, Day Pitney LLP
Susan R. Huntington, Day Pitney LLP

Update on HIPAA Enforcement and Best Practices
Kimberly J. Gold, Norton Rose Fulbright LLP

Open Membership Calls

AMCTH Open Membership Call
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Kate Gallin Heffernan, Verrill Dana LLP

Antitrust Practice Group Open Membership Call
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John Carroll, King & Spalding LLP
Aimee E. DeFilippo, Jones Day
Ashley M. Fischer, McDermott Will & Emery LLP
Dionne C. Lomax, Mintz Levin Cohn Ferris Glovsky & Popeo PC
Joshua H. Soven, Gibson Dunn & Crutcher LLP

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Stanley W. Crosley, DrinkerBiddle
Austin O'Flynn, Dignity Health
Jeffery W. Short, Hall Render Killian Heath & Lyman

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Gregory D. Anderson, HORNE LLP
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Nicole F. DiMaria, Chiesa Shahinian & Giantomasi PC
Mary Beth E. Fortugno, Bass Berry & Sims PLC
Emily Black Grey, Breazeale Sachse & Wilson LLP
Marta J. Hoffman, Independent Contractor
Neerja Razdan, University of Maryland Medical System

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Christopher Dang, Quarles & Brady LLP
Nichole Hines, Humana
John A. Mills, Nelson Hardiman LLP
Emily A. Moseley, Strategic Health Law
Brian Vick, Blue Cross Blue Shield of North Carolina

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Andrea M. Ferrari, HealthCare Appraisers Inc
Vivian M. Gallo, Halifax Health
Montrece McNeill Ransom, Office for State Tribal Local and Territorial Support CDC
Kimberly S. Ruark, BakerHostetler
Ashley L. Thomas, Baker Donelson Bearman Caldwell & Berkowitz PC

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Daniel J. Hettich, King & Spalding LLP
Matthew William Horton, Baker Donelson Bearman Caldwell & Berkowitz PC
Claire Miley, Bass Berry & Sims PLC
Jeffrey S. Moore, Phelps Dunbar LLP
Ross E. Sallade, Polsinelli PC
Jeanne L. Vance, Salem & Green PC
Judith A. Waltz, Foley & Lardner LLP

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Lona Fowdur, Economists Incorporated
Amy MacFarlane, New York State Office of the Attorney General
Gregory Vistnes, Charles River Associates

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Anil Shankar, Foley & Lardner LLP

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Anil Shankar, Foley & Lardner LLP

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Dan Gerber, University of California Health Law Group
Mary Anne Hilliard, Children's National Health System
James Moloney, Cain Brothers

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Matthew W. Caspari, U.S. Department of Behavioral Health
Anna S. Whites, Anna Whites Law Office

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Suzette Elizabeth Gordon, Bronx Partner for Health Communities
Jennifer Lohse, Hazelden Betty Ford Foundation
Kelly J. Epperson, Rosecrance Health Network

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Jennifer Lundblad, Stratis Health
Dawn Pepin, Centers for Disease Control and Prevention
David Weil, Quorum Legal Services

Medical Staff Rules, Regulations, Policies, and Procedures: Maximizing MSP and Staff Attorney Roles, Part II: Peer Review (Intermediate)
Chris Hinson, Retired
Erin L. Muellenberg, Polsinelli LLP

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Sara Cameron, HSHS St. John's Hospital
Jennifer Hansen, Hooper Lundy & Bookman PC

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Bernabe Icaza, UF Health Shands Legal Services
Greg V. Moser, Procopio
Andrea M. Ferrari, HealthCare Appraisers Inc

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Martha R. Karam, Rogaliner
Col. Noel C. Pace, 411th Hospital Center
David Weil, Quorum Legal Services

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Montrece McNeill Ransom, Centers for Disease Control and Prevention

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Developing Effective Lines of Communication in Health Care Compliance
Marla Susan Berkow, Gateway Foundation

Legal Challenges in Precision Medicine
Kinal Mahesh Patel, Squire Patton Boggs

AHLA Weekly

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Rebecca L. Burke, Powers Pyles Sutter & Verville PC
Christina Learman Krysinski

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Ashley Thomas, Baker Donelson

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Shoshana S. Speiser, Manatt Phelps & Phillips LLP

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Kristen Johns, Waller Lansden Dortch & Davis LLP
Thejasree Kayam, Feldesman Tucker Leifer Fidell LLP
Kim Harvey Looney, Waller Lansden Dortch & Davis LLP
W. Kenneth Marlow, Waller Lansden Dortch & Davis LLP
Michaela D. Poizner, Baker Donelson Bearman Caldwell & Berkowitz PC
Glenn P. Prives, McElroy Deutsch Mulvaney & Carpenter LLP
Brandon M. Schirg, Waller Lansden Dortch & Davis LLP
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Behavioral Health Care: The New Frontier of Fraud and Abuse?

By Jennifer Lohse, Hazelden Betty Ford Foundation;
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Behavioral health parity,[1] increased focus on whole-person integrated care, the inclusion of behavioral health services as essential benefits under the Affordable Care Act, and the national opioid epidemic have all played a part in moving mental health and substance abuse treatment out of the shadows of mainstream health care. Providers and health systems across the country are integrating behavioral health services into their offerings, although the majority of services are provided outside of traditional environments. Only a handful of years ago, many behavioral health providers operated outside of both the health insurance marketplace, as well as state and local health care benefit programs. This is no longer the case, as most patients have insurance that will help them access mental health and substance abuse treatment services—both in-network and out-of-network. However, in response to considerable abuses on the part of some behavioral health providers, states are beginning to strengthen their licensing standards and state fraud and abuse statutes—and not just for providers that receive public funds. Interested stakeholders are calling on federal and state agencies that oversee the industry to use their regulatory authority to pursue unethical practices that pose significant risk of harm to patients.

Unethical Practices

Patient Brokering

Patient brokering is the exchange of money or something else of value for the delivery of a patient to a behavioral health provider—likely for substance use disorder treatment. National news reports are replete with tragic stories of people brokered away from their home state to another state for substance abuse treatment.[2] The brokers are making promises about guaranteed admission to treatment facilities or payment for plane tickets and other expenses necessary to get the patient to the provider.[3] In turn, the treatment providers reportedly are paying the brokers thousands of dollars for each patient that they get through the door.[4] Patients seeking help for mental health and substance abuse disorders are uniquely vulnerable to this type of "help," as some of them have exhausted good will with family and friends and view this as the "last chance." Not all states have fraud and abuse or conflict of interest statutes that prohibit such behavior when the patient is not a government health care program participant.

Exploitation of Insurance Benefits

Some patient brokering scams procure insurance policies for patients seeking help and only pay the premiums for the first 30 or so days.[5] After the brokers stop paying for the policy, the

provider denies services and the patient is out of treatment—in a state sometimes far away from their support network.[6] Another common arrangement includes forgiving a patient for his portion of financial responsibility (i.e. patient deductible or copay) to induce the patient to choose the provider—sometimes advertising that the patient will not have any cash responsibilities. As with most out-of-network services, no contract exists between the provider and the insurance company, and therefore the provider is not subject to pre-authorization requirements, medical necessity criteria, or clinical review of the appropriateness of the treatment provided.[7] In some cases, there is little documentation about what services actually were provided to the patient. Another scheme unique to substance abuse treatment involves out-of-network providers exhausting the full range of substance use disorder treatment benefits (i.e. inpatient, partial hospitalization, and outpatient services) without actually changing the level of care or treatment plan for the patient. After exhausting the benefits, the patient is discharged due to non-coverage. This practice leaves the patient without the coverage options for continued treatment. Of course, there are also inherent risks for billing for services not actually performed, or performed at a lower-level of care.

Suspect joint ventures are nothing new, particularly when it comes to relationships between laboratories and referral sources with a financial interest. Some patients have found themselves owing more for laboratory services than for the actual substance use treatment inpatient stay.[8] In its investigation focused on Florida substance use treatment fraud, *The NY Times* noted a significant connection to sober homes, treatment facilities, and laboratory services fraud, stating that "[t]o increase profits, many treatment centers and labs overbill insurance companies for unnecessary tests, including of urine, blood and DNA. Some have billed insurance companies thousands of dollars for a urine test screen. Patients often unnecessarily undergo multiple urine tests a week."[9]

Sober Homes

Sober homes are living establishments that provide a bridge from a drug or alcohol treatment provider to a mainstream living arrangement. Many times rules and curfews are imposed to help provide the structure and accountability a newly sober person needs to build self-efficacy skills and develop new support systems to aid in ongoing recovery. In most states, sober homes have little to no licensure requirements and are subject to minimal oversight. Recent enforcement activity has shed light on the need for consistent standards, regulation, and oversight by state and federal authorities to prevent exploitation and abuse of patients.[10]

[I]n response to considerable abuses on the part of some behavioral health providers, states are beginning to strengthen their licensing standards and state fraud and abuse statutes—and not just for providers that receive public funds.

Sober homes serve a vital and necessary role in the substance abuse treatment continuum, yet this level of service seems particularly vulnerable to exploitation, often in the form of suspect arrangements with treatment and laboratory providers.[11] Reduced or free rent is offered to a patient to attend a specific treatment program, while the sober home collects a fee from the program in exchange for the arrangement.[12] Other types of kickback relationships exist that are disguised as "consulting" or "supervision" fees.[13] Many times sober homes will use regular drug testing of residents to promote accountability and help keep people sober. However, when those drug tests become excessive, including several times a day or week without cause, the arrangement can quickly become abusive and illegal.[14]

Psychiatric Hospital Practices

Earlier this year, a psychiatrist from Houston, TX was the sixteenth person to be convicted by a federal jury for the part he played in a local hospital's fraudulent scheme involving the submission of $158 million in false claims to Medicare.[15] Dr. Riaz Mazcuri was the third physician to be convicted in the scheme and faces years in federal prison.

The scheme involved the payment of bribes and kickbacks by Riverside General Hospital to various group home owners and nursing home employees in exchange for sending Medicare patients to Riverside's supposed partial hospitalization programs (PHPs). Partial hospitalization is a medically supervised and therapeutically intensive outpatient psychiatric service that provides an alternative to inpatient hospitalization.[16] It is a higher level of care than outpatient psychiatry, but does not require an overnight stay. Patients with moderate to severe psychiatric issues often are referred to PHPs after outpatient visits with a psychiatrist fail to meet their mental health needs.

According to evidence presented at trial, Dr. Mazcuri indiscriminately admitted and readmitted patients into Riverside's PHPs, sometimes for periods of years. Many of these patients had been diagnosed with Alzheimer's or Dementia and lacked the capacity to participate in the treatment being provided in these PHPs and thus did not qualify for placement in such programs in the first place. Other trial evidence demonstrated that Dr. Mazcuri only visited the PHPs once a week to briefly see patients and sign necessary documents, which included falsified medical records. In total, Dr. Mazcuri personally billed

Medicare more than $4.5 million in false claims and signed documents enabling Riverside to fraudulently bill Medicare approximately $55 million.[17]

Unfortunately, Riverside's admission practices are not the first of their kind. Hospitals in states like New Hampshire recently have been under fire for holding patients in emergency rooms (ERs) for weeks at a time while they await involuntary commitment to the single psychiatric hospital in the region. Earlier this year, the wait list at New Hampshire's state-run psychiatric hospital was 68 patients long, resulting in patients sitting in ERs across the state, many of whom were admitted there involuntarily and could not by law be released until they could be committed to the psychiatric hospital.[18] These patients lack the legal footing, and often the mental capacity, to challenge what is happening in court. Although New Hampshire law requires that involuntary psychiatric patients receive a hearing within 72 hours of admission, the clock does not start running until the patient has been admitted to the state-run psychiatric hospital, not the ER where the patient was involuntarily admitted in the first place. The result: patients waiting days and even weeks before being heard in court. Things got so bad in New Hampshire that a judge was prompted to petition the New Hampshire Supreme Court to hear a case on whether holding patients in the ER for weeks while they await involuntary commitment to the state-run psychiatric hospital violates the law or patients' constitutional rights.[19] The court declined to take the case. In 2014, the Washington Supreme Court ruled this same practice by ERs was unlawful.[20]

Illegal Prescribing Practices

One of the unfortunate realities of the opioid crisis that plagues so many U.S. cities is the part some physicians continue to play in perpetuating the crisis. Over the last ten months, 37 of the Drug Enforcement Administration's (DEA's) investigations of its registrants have resulted in arrest or prosecution.[21] Over the last decade, 378 criminal cases were brought against doctors for distributing controlled substances outside of legitimate medical need. U.S. attorneys' offices charged 249 of the 378 doctors and state authorities charged 131; 272 of the doctors who pled or were found guilty were sent to prison.[22]

More recently, a Kentucky physician and his wife were sentenced to 180 and 80 months in prison, respectively, for knowingly providing controlled substance prescriptions to individuals who were diverting the drugs for sale, pre-signing controlled substance prescriptions later filled out by non-DEA licensed staff, and falsifying urine drug screens. A federal jury convicted the couple on numerous counts of conspiracy to commit drug trafficking, illegal distribution of controlled substances, maintaining a premise for drug distribution, money laundering, and health care fraud.[23]

While many of these crimes are discovered by authorities investigating federal program fraud and abuse, those providers who purposely avoid billing federal programs for health care services are not impervious from discovery either. A Connecticut psychiatrist was sentenced to 26 months in prison earlier this year for prescribing controlled substances including Adderall and Xanax to patients who paid for cash for the psychiatrist's services.[24] Similar stories resulted in convictions of psychiatrists in New York, Pennsylvania, and California this year.

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Response to Unethical Practices

As with the health care industry generally, the behavioral health care community includes both high-quality, ethical providers and some unethical providers who seek to profit by exploiting a vulnerable population. The challenge for all who have a nexus to this particular treatment industry—other providers, referral sources, payers, and government regulators—is distinguishing the good actors from the bad actors.

The current federal regulatory scheme does not adequately address fraud and abuse in the behavioral health care arena in the same way and to the same extent as it does in the medical health care sphere. The primary enforcement tools to combat health care fraud and abuse include the Anti-Kickback Statute (AKS), the physician self-referral law (Stark Law), and the federal False Claims Act (FCA). Because the behavioral health care industry has for-profit providers that simply do not accept publicly funded patients, federal fraud and abuse statutes typically do not apply to these providers. For example, the AKS prohibits payments for the referral of patients when those health care services are paid for by federal health care programs such as Medicare or Medicaid.[25] Similarly, because the Stark Law only applies to physicians providing "designated health services" to Medicare and Medicaid patients, most for-profit behavioral health providers will be immune to the threat of Stark enforcement.[26] Finally, the FCA prohibits a person from submitting false claims for payment by the federal government.[27] Because the unethical practices described above generally involve commercial or private payers, many efforts to respond to unethical behaviors in the addiction treatment field have focused more on local and state laws with enforcement by regulatory bodies in those jurisdictions.

Many states have their own false claims acts; however, these laws will apply only if the provider's behavior impacts state funds. In contrast, state laws prohibiting insurance fraud have a more expansive reach and generally prohibit providers from submitting any false information or false claims to a commercial or private payer. State statutes generally require intentional conduct and only apply to knowingly fraudulent conduct. In the examples of unethical conduct described above, if the provider is actually providing the care listed on the claim form and the unethical conduct was to induce the patient to use that specific provider, state insurance fraud statutes would not necessarily apply unless the care was not medically necessary or was not being provided. The key difference between the state insurance fraud laws and federal fraud and abuse laws is that the state insurance fraud statutes apply to claims submitted to commercial payers, rather than government payers. For example, in California, two physicians recently were accused of writing unnecessary prescriptions for urine drug tests that were not medically necessary and overbilling insurance companies for the collection of urine for drug screens.[28] Still, state insurance fraud laws have not routinely been used in the same manner as federal health care fraud and abuse statutes to respond to the prevalent unethical practices in the behavioral health industry.

The current federal regulatory scheme does not adequately address fraud and abuse in the behavioral health care arena in the same way and to the same extent as it does in the medical health care sphere.

Florida recently passed new legislation to respond to the problematic practices that were not necessarily addressed under the existing regulatory scheme. In May 2017, the Florida legislature unanimously passed a comprehensive bill aimed at regulating the addiction treatment industry, including provisions directed at providers, sober homes, and call centers. The Practices of Substance Abuse Service Providers Act amends licensure requirements for providers to require accreditation; prohibits referrals to uncertified sober homes; expands the activities that are prohibited as deceptive marketing practices; expands the list of items that may not be used to induce patient referrals; creates a minimum $50,000 fine for patient brokering; adds patient brokering to the list of prohibited "racketeering activities"; and requires substance abuse marketing service providers, including call centers, to be licensed.[29]

The regulation of sober homes can be difficult because it requires consideration of the Americans with Disabilities Act (ADA) and the Fair Housing Act (FHA) as many people in recovery are considered protected under both statutes. To be compliant, the regulations cannot focus on preventing sober homes entirely, but instead must focus on protecting patients. Although cities may be hesitant to issue regulations in this area given the FHA and ADA issues, the Department of Justice and U.S. Department of Housing and Urban Development recently released a joint statement with guidance on how to regulate sober homes while staying compliant with the FHA.[30]

State attorney general offices wield significant power to investigate the fraudulent and dangerous practices of treatment providers. For example, the Massachusetts Attorney General recently launched an investigation into an insurance fraud scheme where patients were sent for treatment to out-of-state providers for the purpose of exploiting their insurance benefits.[31] Additionally, 41 state attorneys general also recently announced a joint effort to investigate opioid manufacturers' marketing and selling practices.[32] The recent settlements obtained by the New York Attorney General's office for violations of state and federal parity laws show the influence that the state attorneys general can have over questionable practices.[33]

Google recently made headlines in the addiction treatment industry when it limited Google search ads on rehab related searches in September 2017.[34] Through the Google AdWords system, treatment providers (like any other business) could bid on search terms and, if they won the bidding, their ad would appear in response to those search terms. Anytime someone would click on the ad, the provider would owe Google a fee. Previously, Google reportedly was earning $100 or more per click on each ad for addiction treatment.[35] After numerous complaints, its own internal investigation, and consultation with experts, Google decided to restrict ads in the addiction treatment category due to misleading information and unscrupulous behavior.[36] The limits Google placed on its AdWords program, however, hit ethical and unethical providers alike. Google reportedly stated that they will continue refining which searches in this sphere will be eligible for ads and which searches will be ineligible.[37] Providers have concerns that consumers will rely more on Google Maps business listings, which are notorious for being hijacked by providers and call centers who list their own phone numbers.[38]

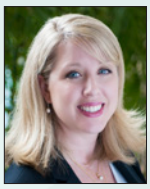
In the mental health field, state senators continue to propose legislation aimed at curbing unethical psychiatric admission practices through increased funding of mental health services. In June 2017, Governor Chris Sununu of New Hampshire signed into law House Bill 400, which, among other things, requires the state's Department of Health and Human Services to develop a comprehensive ten-year plan for the state's mental health system that includes recommendations to reduce the number of individuals waiting in ERs for inpatient psychiatric services and a specific plan to ensure the protection of individuals' statutory

Federal fraud and abuse investigations likely will only increase the yield of enforcement activity in both the mental health and substance abuse fields as the federal government and states search for wasted resources and treatment capacity.

and due process rights when they are subject to involuntary admissions and awaiting transition to a psychiatric hospital.[39]

Disability rights groups, such as Disability Rights California and Disability Rights Maryland, also have played a significant role in educating the community about these issues and ultimately getting high-need patients, such as young adults with severe autism, out of hospital ERs and into alternative care settings, such as private hospitals.[40] Nevertheless, the lack of resources and alternatives for severely mentally ill persons, particularly those with co-occurring disorders and developmental disabilities, continue to persist in more and more states across the country.

Federal fraud and abuse investigations likely will only increase the yield of enforcement activity in both the mental health and substance abuse fields as the federal government and states search for wasted resources and treatment capacity. Simultaneously, the opioid epidemic will continue to disrupt the ethical practice of psychiatry as long as unchecked providers put profits and professional gains ahead of the critical mental health needs of their patients. We expect to see more activity in this area as states and local jurisdictions respond to the unethical practices in behavioral health care through increased enforcement and new legislative initiatives. C



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Member News

Hall Render Killian Heath & Lyman PC is pleased to announce that **Kelly Davis** has joined the firm's Dallas office. Ms. Davis' practice is dedicated to the support of medical malpractice defense and other health care-related litigation.

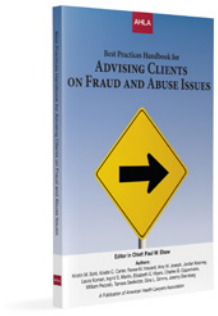
Whiteford Taylor & Preston LLP is pleased to announce that **Kellie L. Newton** has joined the firm as a Partner in its Washington, DC office. An accomplished corporate attorney, Ms. Newton has a sophisticated practice representing nonprofit organizations and privately held companies, including hospitals and health care systems, educational institutions, trade associations, public charities, and foundations.

Whiteford Taylor & Preston LLP is pleased to announce that **Sigrid C. Haines** and **Roseanne M. Matricciani** are listed among the 2018 Super Lawyers in Maryland.

Firm News

Hall Render Killian Heath & Lyman PC has announced that **Jon Boguth, Lauren Hulls, Joe Krause, Julie Lappas, Rene Larkin, Sara MacCarthy,** and **Katie Miller** have been named Shareholders. Mr. Boguth has extensive experience drafting and negotiating agreements for IT products and services used across health systems. Ms. Hulls practices in the area of health care law with a focus on transactional, regulatory, and reimbursement matters. Mr. Krause focuses his practice on corporate and regulatory work for health care clients. Ms. Lappas' practice involves counseling health systems on payer contracting and corporate compliance issues. Ms. Larkin counsels clients on a large range of real estate matters. Ms. MacCarthy's work involves the representation of health care entities with regard to health care regulatory issues. Ms. Miller practices in the area of health care law with a focus on regulatory, compliance, corporate transactional, and physician integration matters.

Author Thanks



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1 Health Care Reform and the ACA

—Katrina Pagonis and Stephanie Gross, Hooper Lundy & Bookman PC

A year after President Trump took office, the Affordable Care Act (ACA) remains the law of the land, but its future is uncertain. Although Republican efforts to fully "repeal and replace" the law have been unsuccessful so far, the Tax Cut and Jobs Act[1] repeals a central pillar of the ACA—the individual mandate—in 2019, meaning that either we will discover how insurance markets fare without a penalty for failing to maintain coverage or Congress will intervene with additional health reform legislation. The administration has taken steps to provide consumers, insurers, and states with greater flexibility in satisfying the ACA's other requirements and shortened the enrollment period for the ACA's health insurance exchanges (Marketplaces). Despite this abbreviated open enrollment period, approximately 8.8 million signed up for coverage through HealthCare.gov.[2]

Congress: Efforts to Repeal & Replace the ACA and Tax Reform. Much of the health policy news over the past year focused on Republicans' efforts to make good on promises to repeal and replace the ACA. The House passed a bill that would have repealed much of the ACA by eliminating the individual and employer mandate penalties; giving individual and small group health plans greater flexibility in setting premiums, benefits, and cost-sharing; allowing states to waive certain ACA protections for individuals with preexisting conditions; repealing the ACA's Medicaid expansion; and transforming Medicaid into a block-grant program.[3] The Senate ultimately rejected its repeal-and-replace bill, with three Republicans—Senators Susan Collins (ME), John McCain (AZ), and Lisa Murkowski (AK)—voting against it.[4]

After the Senate vote, Congress shifted its attention to tax reform legislation, which was enacted last month and signed into law on December 22, 2017. Along with a sweeping overhaul of the tax code, the new law repeals the individual mandate, a core component of the ACA. Some analysts caution that this will seriously threaten the stability of the individual and small group health insurance markets, including the Marketplaces. The Congressional Budget Office (CBO) estimated that between 4 and 13 million individuals would lose insurance coverage and that premiums in the individual and small group insurance markets would rise about 10% as a result of this provision.[5] Others hold the view that the penalty for failure to have health

insurance was never large enough to significantly influence enrollment decisions, so its elimination will not dramatically alter insurance markets.[6]

There has been some discussion of Congress revisiting health reform as early as this year, but any repeal-and-replace effort may be even more challenging for Republicans after Alabama's special election for Senate. Once Doug Jones (D-AL) is sworn in, the Republicans will hold a slim 51-49 majority in the Senate.

Executive Action & Legislative Efforts. While legislative action to repeal and replace much of the ACA remains elusive, the Trump administration has taken steps to limit the ACA's reach. Leading up to the 2018 open enrollment period for the Marketplaces, the administration cut the outreach and marketing budget to $10 million (a 90% reduction), cut grants to enrollment assistance groups known as Navigators to $36.8 million (a 40% reduction), and adopted a six-week open enrollment period (a 50% reduction) for HealthCare.gov states. State-based Marketplaces like Covered California were insulated from these changes because they fund their own marketing, outreach, and enrollment efforts and can adopt a longer open enrollment period.

In addition, on October 12, the administration announced that it would no longer make payments to insurers for cost-sharing reductions (CSRs), taking the view that there is no permanent appropriation for these funds.[7] These payments fund the offering of CSR-variant silver plans that have lower deductibles, copayments, and out-of-pocket spending limits for low-income Marketplace enrollees.

The House of Representatives successfully challenged these payments in the U.S. District Court for the District of Columbia, but Judge Collyer's order enjoining the administration from making CSR payments remains stayed. Though the administration's appeal continues to be held in abeyance, the parties recently reached a settlement agreement and submitted a joint motion to the district court seeking an "indicative ruling" that, on remand, the court would vacate its injunction.[8] As the joint motion explains, the administration already decided not to make CSR payments, "obviat[ing] the need to resolve those issues in an appeal in this case." The parties argued that an indicative ruling from the district court would allow the litigation to come to a close without the D.C. Circuit deciding whether the ACA creates a permanent appropriation for CSR payments.[9]

Separately, 18 states and the District of Columbia sued to enjoin the federal government from cutting off these payments. The states were unsuccessful in obtaining injunctive relief in November, but a ruling on the merits is expected in 2018.[10]

The effect of the absence of CSR funding on 2018 premiums has varied by state. In 36 states, Marketplace insurers loaded the cost of lost CSR payments into the silver tier premiums, an approach that maximizes the other ACA subsidy—premium tax credits. As a result, most individuals shopping on the Marketplace in these states gained enhanced buying power.[11] In a few states, however, insurers either did not account for the loss of CSRs or "broadly loaded" the cost of CSRs across all metal tiers, thereby diluting the buying power of premium tax credits.

To mitigate these potential sources of instability, Senators Patty Murray (D-WA) and Lamar Alexander (R-TN) announced a bipartisan effort to affirmatively appropriate funds for CSRs for two years. This legislative fix might render ongoing litigation over the CSRs moot. The proposed bill also would direct the administration to engage in outreach efforts to encourage enrollment through the Marketplaces, and would provide some flexibility to Marketplace plans.[12] Though the CBO announced that the bipartisan legislation would reduce the deficit, the bill's future remains uncertain at the time of writing.[13]

From the standpoint of rulemaking, the Departments of Health and Human Services (HHS), Labor, and Treasury adopted market stabilization regulations in early 2017 that, among other things, imposed more stringent requirements for special enrollment periods, shortened the 2018 open enrollment period, and ended federal oversight of Marketplace plans' network adequacy.[14]

Additional ACA rulemaking is expected in 2018, starting with the 2019 Notice of Benefit and Payment Parameters. Each year, this rule sets forth parameters and provisions relating to the Marketplaces, including the risk adjustment program and user fees to fund Marketplace activities. The proposed 2019 Notice of Benefit and Payment Parameters is notable in that it would provide states with greater flexibility to define essential health benefits and enhance the state role with regard to plan management on the federal Marketplace.[15]

Lastly, a proposed rule on association health plans (AHPs) was published on January 5, 2018. This was the first rule to come out of the White House's October 12, 2017 executive order prioritizing the loosening of restrictions on AHPs, short-term, limited-duration insurance (STLDI), and health reimbursement arrangements. STLDIs and, to a lesser extent, AHPs, are not subject to many of the ACA's health insurance market reforms.[16] Some analysts warn that more liberal rules for AHPs and STLDIs would draw younger and healthier individuals away from the Marketplaces, resulting in premium increases for a sicker Marketplace population.

Outlook for 2018

The day the Senate bill was rejected, President Trump announced on Twitter that he expected the ACA to "implode" on its own, even without legislative action.[17] For now, though, it seems that ongoing uncertainty over the ACA's fate has not proven too disruptive to health insurance markets. Though major national insurance companies have continued to withdraw their offerings from the Marketplaces, in 2018, there are no "bare counties" without health plans participating in the Marketplaces.[18] Early enrollment was better than expected, but ultimately enrollment numbers fell below 2017 levels, likely due to an abbreviated enrollment period, consumer confusion, and significant marketing cuts.

In 2018, issuers will make projections about the effects of the repeal of the individual mandate on enrollment numbers and the risk profile of insureds and will continue tracking Marketplace enrollment numbers, the shifting regulatory landscape for the Marketplaces, and the likelihood of further legislative changes (whether stabilizing or destabilizing) in

deciding on their 2019 Marketplace participation and premium rates. Individuals, particularly those without employer-sponsored coverage, will decide whether to take up or retain coverage without the individual mandate. Providers likewise will monitor the impact of the repeal of the individual mandate, other health reform initiatives, and issuer responses on the uninsured rate, Medicaid coverage and reimbursement, and patients' cost-sharing obligations.

Fraud and Abuse: the More Things Change, the More They Stay the Same

—Kevin E. Raphael, Pietragallo Gordon Alfano Bosick & Raspanti LLP

The health care industry in 2018 will feature more horizontal consolidation of hospital systems and the testing of vertical integration between a pharmacy (CVS) and an insurance company (Aetna). Opioid litigation will remain in the spotlight, while commercial insurance carriers will increasingly enter the litigation fray to recover costs from various alleged abuses by providers, opioid manufacturers, compound pharmacies, and laboratories. Common across all these new or expanding areas of focus will be the typical fraud and abuse analyses under the Anti-Kickback Statute, Stark Law, and the False Claims Act. State laws likely will play a greater role in fraud and abuse litigation in 2018, although the challenged alleged conduct also will be familiar: kickbacks, improper financial relationships, and medically unnecessary services.

Opioid Enforcement and Litigation. Already a Department of Justice (DOJ) focus in 2017, opioids will remain a major focus of 2018 activities. Greater federal enforcement efforts against providers will be the norm, as will increased state law enforcement investigation and prosecution efforts. Expect more licensing board actions against health care professionals in conjunction with these criminal enforcement efforts.

Additional litigation against opioid manufacturers nationwide is likely, filed by local governments that have been hit hardest by the opioid crisis. This litigation will seek recovery for the expenses, health care and otherwise, incurred by these governmental units related to opioid addiction. Further, expect commercial health care insurance companies to experiment with related suits against prescribing providers to recover the costs related to the opioid prescriptions and the treatment provided to those subsequently addicted insureds.

Fraud and Abuse Litigation by Commercial Insurance Carriers. Similarly, commercial health insurance, automobile insurance, and workers' compensation carriers likely will increase the use of fraud-based civil lawsuits against providers in state and federal courts. State insurance fraud laws, state whistleblower laws, and state laws governing workers' compensation will feature prominently. These lawsuits will be premised on the following: allegations of kickbacks and other illegal financial relationships between providers and ancillary services, such as pharmacies and laboratories; violations of state and insurance fraud laws prohibiting financial inducements for referrals; and failure to comply with state licensing requirements.

Compounding Pharmacies. The federal government focused on compounding pharmacies and prescribing physicians in 2017, securing a number of convictions related to the use of kickbacks and the lack of medical necessity for the prescribed drugs. Compounding pharmacies increasingly will be scrutinized in 2018, given the increased costs of compound drugs compared to generic or brand named equivalents. The marketing relationships employed by compounding pharmacies will remain a focus and will be reviewed for the existence of kickbacks or other improper financial inducements for referrals.

Laboratories. Laboratory fraud, including that related to toxicology screenings affiliated with drug treatment programs, likely will become a hot topic in 2018, particularly as the opioid litigation delves deeper into the course of practice in prescribing opioids and uncovers the details of these relationships between providers and laboratories. Anti-Kickback concerns will feature prominently in investigations and litigation surrounding the referral and provision of toxicology screening services by laboratories.

Post-Escobar Application of Materiality Standard. The application of *Escobar*'s materiality standard to a variety of Medicare regulations in implied certification False Claims Act cases likely will be an issue to watch in 2018. False Claims Act litigation may be significantly impacted, as defendants assert that the Medicare regulations they are alleged to have violated are not material to the government's decision to pay the relevant claims.

Fraud and Abuse Challenges to Integration. Both the vertical and horizontal integrations in the health care market will highlight typical fraud and abuse concerns of Anti-Kickback Statute and Stark Law compliance. Will the new structures created by these integrated entities, and the newly formed relationships between physicians and the consolidated entities, fully address these compliance concerns?

Meet the New Boss, Same as the Old Boss:[19] Ransomware Will Continue to Vex Health Care in 2018

—Leonardo Tamburello, Willis Towers Watson

2018 likely will see ransomware's continued exploitation of known vulnerabilities that will be multiplied by the ever-increasing attack surface thanks to "smart" products, including medical devices, that make up the "Internet of Things" (IoT).

Until underlying vulnerabilities such as running unpatched or outdated and unsupported operating systems are significantly reduced or eliminated, ransomware will continue to proliferate. In 2017, one-fifth of health care organizations in the United States and United Kingdom responding to a poll reported still having Windows XP machines on their network. Slightly less (18%) reported that they still have connected medical devices running Windows XP on their networks.[20] Companies that continue to rely on Windows XP do so at their

own considerable risk considering Microsoft ended support for Windows XP in April 2014, and no longer provides security updates or technical support for it.[21]

Coming into 2017, individual consumers were the most common victims of ransomware. WannaCry and Petya/NotPetya, which were designed to spread laterally inside a network, conclusively reversed this trend as business networks were crippled by these forms of malware.[22] Both of these ransomware variants used the same known exploit for which a patch was available as a propagation mechanism, though Petya and its variants were more advanced in their ability to detect and evade anti-virus defenses.[23] The Petya family also added another fiendish twist: although they presented as typical ransomware demanding a payment in exchange for a decryption key, in reality there was no capability to restore the encrypted files. Consequently, if a payment was made, nothing would be recovered. In effect, it was disk-wiping malware masquerading as ransomware.[24]

The ransomware attacks led by the WannaCry and the Petya families affected numerous health care entities including a health system spanning parts of Pennsylvania, Ohio, and West Virginia; a prominent U.S. pharmaceutical manufacturer; a multinational law firm; and at least one major health care vendor.[25] Fueled by existing and newly discovered exploits, the flood of new ransomware variants continues. In the first half of 2017, researchers identified at least 71 new families of ransomware.[26]

This type of destructive malware could find new fertile ground among medical devices and the estimated 22.5 billion other devices comprising the IoT expected by 2021. In the general consumer marketplace, these "things" include devices such as toys, thermostats, door locks, and cars.[27] While the hacking of consumer devices can have serious consequences, the stakes are considerably higher in the health care space where "smart" devices such as insulin delivery systems, inhalers, and ingestible sensors are being developed.[28]

In August 2017, the Food and Drug Administration (FDA) and Department of Homeland Security warned that medical devices that contain configurable computer systems, including pacemakers, could be vulnerable to intrusions and exploits.[29] The vulnerabilities identified by these warnings included improper authentication that could be bypassed or compromised, potentially allowing a nearby attacker to issue unauthorized commands to the device; improper controls on power consumption, which could permit an attacker to repeatedly send commands to reduce battery life; and missing encryption between the device and programmers and home monitoring units.[30] Although these exploits would require an attacker with a high degree of skill, the manufacturer took them seriously enough to develop firmware updates for affected devices but stopped short of requiring them to be implemented for all patients. Instead, it recommended that providers and patients "discuss the risk and benefits of cybersecurity vulnerabilities and associated firmware update at the next regularly scheduled visit."[31] It is not yet clear if a physician consultation regarding "cybersecurity vulnerabilities and associated firmware update" will be widely reimbursable by payers anytime soon, but presumably we can at least expect an applicable ICD-10 code in the near future.

More recently, microprocessor manufacturer Intel announced the discovery of four firmware vulnerabilities affecting several lines of its processors. This means that potentially millions of PCs, servers, and IoT devices are at risk. Although it remains unclear how swiftly these flaws might be leveraged into actionable exploits, vendors such as HP, Dell, and others have already completed patches addressing them.[32] It remains up to individual consumers and system administrators to ensure that patches like these are actually implemented.

Until underlying vulnerabilities are significantly reduced or eliminated through retirement of outdated and unsupported applications like Windows XP, and patching becomes the rule rather than the exception, ransomware will continue to proliferate in 2018 and beyond.

4 Payment Reform Model Trends in 2018

—Daniel J. Hettich, King & Spalding LLP

While payment reform has been a hot topic in health care for the past several years with the prior administration famously promising to tie 90% of all Medicare fee-for-service payments to quality or value by 2018, the goals of the new administration are far less clear in this regard, particularly since virtually all of the major payment reforms were inherited from the previous administration.

2018 promises to be the year in which the new administration's full vision of payment reform comes into focus. That vision is likely to be marked by clear shifts in emphasis but not wholesale refutations. This prediction is bolstered by HHS Secretary nominee Alex Azar's testimony during his confirmation hearing in which he called the "launching [of] so many of the alternative payment models" "one of the great legacies of Secretary Burwell's tenure." The specific trends in each of the payment reform programs are discussed below.

Bundled Payment Programs. Perhaps the greatest uncertainty surrounded the fate of the mandatory bundled payment programs for hip and knee replacements (commonly referred to as the Comprehensive Joint Replacement, or CJR program), heart attacks, and cardiac bypass surgery. The dissolution of all such mandatory payment programs was a distinct possibility, especially since the then-HHS Secretary Tom Price, as a congressman, sent a letter to the Centers for Medicare & Medicaid Services (CMS) calling the CJR program a "high-risk government-dictated reform[] with unknown impacts." In the last weeks of 2017, however, CMS issued a final rule leaving the mandatory CJR program intact in 33 of the original 67 geographic areas while rescinding the cardiac bundled payment programs entirely. In that same rulemaking, CMS promised to develop more *optional* "bundled payment model(s) during CY 2018 that would be designed to meet the criteria to be an Advanced APM [alternative payment model]." This promise is particularly important to physicians since currently there are limited options for participation in Advanced Alternative Payment Models (APMs).

An early sign of the administration's focus in 2018 is CMS' rollout on January 9, 2018 of the next-generation Bundled Payments for Care Improvement (BPCI) program that will take effect after the original BPCI program expires in September of 2018. The BPCI Advanced program remains optional and includes a new iteration of 32 clinical episodes. CMS will set target prices in May of 2018. The program also qualifies as an Advanced APM, making it the first developed by this administration.

Medicare Access & CHIP Reauthorization Act of 2015 (*MACRA).* On November 2, 2017, CMS released its final rule updating for 2018 the Quality Payment Program required by MACRA. Under that rule, 2018 will be "[a] second year to ramp-up the program . . . in preparation for a robust program in year 3 [i.e., 2019]." While CMS made several minor changes in an attempt to make the program more user-friendly, one key change for 2018 is that the Merit-based Incentive Payment System (MIPS) for the first time will factor *costs* in a participant's performance, weighting it at 10%. Participants should take advantage of 2018 as a phase-in period since costs will account for 30% of a participant's score in 2019. As mentioned above, CMS will continue to push for expanded participation in risk-based APMs, which will continue to require at least 8% down-side risk. CMS also plans to add Advanced APMs, such as the Medicare Accountable Care Organization (ACO) Track 1 Plus (1+) Model, and reopen the CPC+ and Next Generation ACO in 2018.

A New Focus for Innovation at the Center for Medicare and Medicaid Innovation (*CMMI).* CMS has been outspoken regarding the big-picture shift it intends to undertake for CMMI in 2018, heralded by the departure of the director of CMMI, Dr. Patrick Conway. The details of that shift, however, are uncertain. According to CMS, in the coming years CMMI will focus on testing models in various areas, including increased participation in APMs; consumer-directed care and market-based innovation models; physician specialty models; prescription drug models; Medicare Advantage (MA) innovation models; state-based and local innovation, including Medicaid-focused models; and mental and behavioral health models.

In September 2017, CMS Administrator Seema Verma penned an op-ed discussing CMMI's initiative to crowd-source ideas for improving Medicare and Medicaid through a public request for information. In the article, Verma stated that improvement "will require health-care providers to compete for patients in a free and dynamic market, creating incentives to increase quality and reduce costs."

As 2018 progresses, we will see to what extent future payment reform models will reflect a downsized role for the government and a trend toward more market-driven, outcome-based, and patient-centered models.

Medicaid Outlook for 2018

—Charles Luband, Dentons US LLP

After a year where legislative proposals in large part focused on potential dramatic changes to the structure of the Medicaid program—including elimination of open-ended federal funding and of the enhanced federal match for expansion populations—changes to the Medicaid program in 2018 are likely to be more incremental (unless major entitlement reform efforts ensue). In fact, even if 2018 brings renewed efforts to repeal and replace the ACA, it seems unlikely that Medicaid reform will be the centerpiece it was in the 2017 legislative efforts. Additionally, Medicaid was in some ways buoyed by electoral activity in 2017: Maine voters supported Medicaid expansion, notwithstanding opposition of the state governor. The following Medicaid issues are likely to be critical in 2018.

Medicaid Expansion. At present, 32 states and the District of Columbia have expanded their Medicaid programs to cover individuals with incomes up to 138% of the federal poverty level—the expansion made "voluntary" by *National Federation of Independent Business v. Sebelius.*[33] Federal matching for costs of "newly eligible" beneficiaries is 94% for federal fiscal year 2018; this reduces to 93% in 2019, and 90% thereafter. HHS estimated in March 2016 that 20 million people had gained health insurance coverage since 2010, including over 14.5 million in the Children's Health Insurance Program (CHIP) and Medicaid, reducing bad debt for hospitals and shoring up state finances.

Now that repeal of the Medicaid expansion provisions in the ACA appears to be off the table, an important question for 2018 is whether additional states will opt in to the Medicaid expansion. As noted above, over 58% of Maine voters in 2017 voted to require the state to adopt the Medicaid expansion. It seems possible that other states in 2018, particularly Idaho and Utah, could follow Maine's lead and put Medicaid expansion on the ballot. Change in the composition of the Virginia legislature also could result in expansion. One question at the federal level is whether CMS will make it easier or more difficult for states to expand.

Medicaid Waivers. In March 2017, HHS and CMS issued a letter to states indicating a willingness to use Section 1115 demonstration authority to "support innovative approaches to increase employment and community engagement" and "align Medicaid and private insurance policies for non-disabled adults."[34] That letter and CMS' actions since have confirmed that additional change in the Medicaid program in 2018 is likely to occur in the context of Section 1115 demonstration waivers. A number of states have waiver requests pending that include provisions not previously approved by CMS, including work requirements, drug screening and testing, time limits on eligibility, and premiums and disenrollment for non-payment of premiums for non-expansion populations. Some of the requests are part of expansion waivers, while others would apply to non-expansion populations. It is quite possible that Medicaid advocates will litigate if CMS approves some of the waiver requests.

Medicaid Disproportionate Share Hospital (DSH). Medicaid DSH payments, which states can use to reimburse hospitals for Medicaid shortfalls and uninsured costs, were scheduled for substantial cuts in the ACA. These DSH cuts presently are scheduled for federal fiscal year 2018 (i.e. beginning October 1, 2017), although it is possible these reductions will be postponed along with the CHIP extension leftover from 2017. CMS

issued a proposed regulation in July 2017 to implement the required DSH allotment reductions,[35] although it has not yet been finalized. These DSH allotment reductions will substantially impact the ability of states to make Medicaid DSH payments to many hospitals and will be a substantial issue in 2018 if the cuts are not further delayed.

In addition, a number of federal district courts and appellate courts currently are considering a technical legal issue regarding the calculation of the statutory limits that apply to Medicaid DSH payments.[36] These cases have the potential to impact the distribution of DSH payments within states. Decisions are likely in 2018.

Medicaid Managed Care. Managed care is the predominant delivery system in Medicaid. In May 2016, CMS published a comprehensive Medicaid managed care final rule that substantially changed state discretion in implementing and operationalizing managed care.[37] The Trump administration published an informational bulletin on June 30, 2017, which told states that it would not enforce many of the provisions of the 2016 rule.[38] In 2018, CMS likely will indicate whether it intends to allow implementation of the 2016 rule to move forward or whether it intends to rewrite the rules.

One provision of the 2016 rule that CMS allowed to move forward concerned restrictions on the ability of states to require that managed care plans make payments to certain providers. In 2017 there was substantial CMS and state activity on these issues. CMS issued a final rule[39] and an informational bulletin,[40] and many states submitted proposals to states to establish programs under the new framework. This activity likely will continue in 2018.

Hospital Mergers, Acquisitions, and Affiliation Transactions

—Travis G. Lloyd, Bradley Arant Boult Cummings LLP

When it comes to hospital consolidation, what's past is prologue. Increasing reimbursement pressure, changing payment methodologies, and continuing uncertainty regarding the health insurance marketplace are forcing many hospitals and health systems to consider a range of affiliation transactions, from traditional mergers and acquisitions to emerging alternative partnerships, such as the development of clinically integrated networks. By many accounts, hospital deal activity sustained the same torrid pace in 2017 that it has for the past several years,[41] and there is reason to believe the trend will continue in 2018.

The drivers of hospital consolidation are many and varied. Traditional factors like improving access to capital, reducing operating costs, and increasing market share continue to compel hospital deals, but so too do declining reimbursement, emerging value-based payment initiatives, and instability in the health insurance marketplace.

Reimbursement continues to change, and, in the view of many hospitals, for the worse. In March 2017, the Medicare Payment Advisory Commission (MedPAC) issued a report that hospitals' aggregate Medicare margin—that is, the amount by which payment exceeds allowable costs—was -7.1% in calendar year 2015, its lowest level since 2008.[42] Moreover, the report estimated that the margin would decline to roughly -10% by the end of 2017. While the MedPAC report also found that total profitability across all payers remains strong, many hospitals, particularly those with large Medicare and Medicaid populations, are feeling the pinch.

Changes in how—and in how much—hospitals are paid continue to put pressure on the bottom line, leading many health systems to explore their options. Consider the following recent examples:

- DSH payments are made by Medicare and Medicaid to hospitals that treat a disproportionately large share of low-income patients. The ACA has made major changes to DSH payments and provides for significant annual cuts to Medicaid DSH payments (from $2 billion in cuts in 2018 to $8 billion in 2025). These Medicaid DSH cuts were scheduled to go into effect October 1, 2017. While the House has passed legislation to delay the cuts, the Senate has yet to take action.
- For many hospitals, particularly safety-net hospitals in rural areas, the 340B drug pricing program offers a critical subsidy. The program, which allows certain hospitals and other health care providers to obtain discounts on certain outpatient drugs from drug manufacturers, was the subject of a significant change in 2017. Effective January 1, 2018, reimbursement under the program will be cut by nearly 30% for most participating hospitals. Hospital groups filed a lawsuit against HHS to prevent the payment cut from taking effect, and legislation has been introduced to nullify the change, but it remains to be seen whether these efforts will succeed.
- Hospitals also face continued pressure to move patients to less expensive settings. Beginning January 1, 2018, off-campus hospital outpatient departments that are not grandfathered or excepted from the Bipartisan Budget Act of 2015 will be paid 40% of current Outpatient Prospective Payment System rates, representing a 20% decrease from the previous year. Lower rates and strict limits on the relocation of grandfathered facilities create real obstacles for hospitals that seek to grow their community presence.
- Commercial insurers also are increasingly pursuing site-neutral payment policies. For example, in 2017, Anthem announced that it will no longer pay for certain advanced imaging services provided at hospital-based facilities located in nine states.[43] Anthem also indicated that, in certain markets, it would no longer cover non-urgent visits to hospital emergency departments for minor conditions that could be safely treated in lower-acuity settings.[44]

In addition, value-based payment and population health initiatives are prompting many hospitals to consider affiliations and partnerships as a means of acquiring the expertise and support necessary to thrive in the future. Take, for example, the potential impact of MACRA, under which a portion of Medicare payments to physicians will be tied to goals such as quality and cost. MACRA may drive more physicians to join hospitals, as hospi-

tals may be better situated to provide the administrative support necessary to make the most of the new physician payment models. Hospitals that are behind the curve when it comes to building the necessary infrastructure may seek to partner with other hospitals that are further along. Similarly, population health and care coordination initiatives may drive consolidation as hospitals seek to develop and extend service offerings.

With that said, the current administration has not clearly staked out its position on value-based purchasing initiatives, and it has acted to limit the effect of certain bundled payment programs. In 2016, CMS imposed mandatory bundled payment programs for several of the most common procedures for Medicare beneficiaries. With the change in administration, however, CMS reversed course, scaling back the mandatory nature of participation in the Comprehensive Care for Joint Replacement model and canceling altogether several other bundled payment models. CMS also issued a request for industry comments on the future direction of the CMMI, the organization created by the ACA to test innovative payment and service delivery models.

Lastly, uncertainty in the health insurance marketplace likely will add to the pressure felt by many hospitals. In late December, Congress passed a sweeping tax reform bill that repealed the individual mandate at the center of the ACA. As a result, many expect healthy people to leave plans, resulting in a sicker, more expensive group of covered lives, which may cause some insurers to exit the exchanges. According to a November 2017 estimate, repealing the individual mandate would increase the number of uninsured people by 4 million in 2019 and by 13 million in 2027.[45] For many hospitals, such an increase would likely lead to an increase in bad debts, uninsured discounts, and charity care.

In this environment, hospital consolidation likely will be a major theme in the year ahead. While many industry analysts expect traditional merger and acquisition activity to remain robust, alternative structures likely will constitute an increasingly large portion of the hospital consolidation landscape. In particular, hospitals may pursue clinical affiliations, management agreements, or the development of regional networks in an effort to brace for expected changes in payment policy while retaining a degree of independence.

7 Drug Cost/Pricing

—Lindsay P. Holmes and Lee H. Rosebush, BakerHostetler

For yet another year the cost of prescription drugs tops the list of concerns in the health care industry. Why? Drug costs continue to rise and players in the drug industry continue to be unable to explain exactly why drug costs continue to rise. For this reason, the pharmaceutical industry and those in the supply chain remain in the spotlight.

In 2017, Congress continued to struggle to understand and combat rising drug costs. As in previous years, Congress introduced a numbers of bills focused on pricing and transparency in the pharmaceutical industry. A few examples include S. 41[46] requiring HHS to negotiate lower drug prices with pharmaceutical manufacturers via the Medicare Part D program and report to Congress on those negotiations. H.R. 1038[47] would prohibit prescription drug sponsors who participate in the Medicare program from retroactively reducing payment on certain claims submitted by pharmacies. H.R. 1316[48] called for requirements to be placed on pharmacy benefit managers (PBMs) that contract with prescription drug plan (PDP) sponsors, including prohibiting a PBM from requiring "that a plan enrollee use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other pharmacy entity providing pharmacy services in which the PBM has an ownership interest or that has an ownership interest in the PBM." H.R. 1776[49] required, among other things, manufacturer reporting of research and development expenditures, marketing and advertising costs, etc. S. 637[50] allowed "patients and employers to compare PBMs' ability to negotiate rebates, discounts, and price concessions and the amount of such rebates, discounts, and price concessions that are passed through to plan sponsors." S. 637 also required that a PBM, who has contracted with a PDP sponsor or Medicare Advantage organization, pass a minimum percentage of aggregate rebates and discounts to the plan sponsor. While not all of these bills made it far in the legislative process, their existence in rapid succession demonstrates Congress' keen interest in this topic.

Interestingly, introducing new laws was not the only way Congress made the public and the industry aware of its concerns about the cost of drugs in 2017. Based on a bipartisan request by a number of Senators, the U.S. Senate Committee on Health, Education, Labor and Pensions (HELP) held multiple hearings on drug costs, first in June 2017 and then in October 2017. At the second hearing, the Senate HELP Committee brought together members of the pharmaceutical industry including representatives from drug manufacturers, drug wholesalers, PBMs, and pharmacies to discuss how the prescription drug delivery system impacts how much patients pay for those drugs.

Notably, Congress is not the only branch of the federal government taking notice of the drug pricing problem. Early in his term, President Trump emphasized the need to curb drug prices. In March 2017, President Trump tweeted that he was "working on a new system where there will be competition in the Drug Industry. Pricing for the American people will come way down!" In the summer of 2017, a draft Executive Order[51] related to drug pricing circulated among the media and was intended to "[r]educe burdens caused by regulatory and administrative actions that inflate or distort prices for beneficiaries of Federal health programs" and "[r]escind, revise or simplify regulations and other administrative actions that inappropriately or unfairly contribute to higher prices or cost-sharing for medical products for American patients." The draft Executive Order would require certain action from multiple departments within agencies, including FDA, CMS, the Internal Revenue Service, and the Health Resources and Services Administration. The draft Executive Order took a similar tone to the Executive Order[52] issued in January of 2017 requiring that every new regulation be matched with the identification for elimination of two old regulations. Although the draft Executive Order has yet to

make it to a final version, President Trump has indicated, at least publically, that he has no intention of letting the industry off the hook. For example, more recently President Trump took to the twitterverse again to rail against soaring drug prices, including taking a shot at Merck's Chief Executive Officer for "ripoff drug prices." In addition, both President Trump, and his HHS Secretary nominee Alex Azar, have identified the need to lower drug prices as a "top priority."

With respect to specific drugs, there have been several federal and state governmental probes into raising prices of epinephrine and diabetes supplies, including insulin and test strips. For example, there is an ongoing price-fixing lawsuit accusing several companies (both PBMs and manufacturers) of violating both federal and state law when setting prices for diabetic testing supplies. In addition, a number of drug manufactures and a PBM have been the target of questions related to the increase in price of certain critical allergy and diabetes drugs. Several insulin manufacturers also face class actions related to recent pricing. Although the scrutiny and calls for transparency continue, it is unclear what impact it will have on the actual price of drugs in the coming year.

8 The Opioid Epidemic—Legal Issues

—Ellie Bane, Catholic Health Initiatives

"[A] disease that touches too many of our communities—big and small, urban and rural—and devastates families, all while straining the capacity of law enforcement and the health care system."[53] The United States is in the midst of a devastating opioid misuse epidemic that kills at least 90 people per day[54] and has been deemed a "public health emergency" by the Trump administration. As America attempts to address this very real public health crisis, the effects of opioid misuse have created a number of legal issues. This piece provides a general overview of the most common health care related legal issues that have arisen from the opioid epidemic.[55]

Hospitals will face increasing legal challenges in dealing with the opioid epidemic in 2018. Notably, these challenges include dealing with admissions and discharges related to opioid users and also reporting opioid users while remaining compliant with state and federal patient privacy laws. Hospitals must deliver care to opioid users in the same manner as they deliver care to all patients seeking treatment. However, in the case of opioid users, this can create legal challenges regarding what information can be shared with family members, what community outreach can occur, and what social services can be offered to patients.

A significant issue for hospitals is the pain scale implemented in most facilities. Pain scales were used, among other things, as a metric of patient satisfaction and recovery process in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS). However, an unintended consequence of the pain scales was a focus on pain levels, painkillers, and an atmosphere that may have contributed to the current pain medication/opioid epidemic. Hospitals also can expect to be faced with labor and employment shortages as the need for substance abuse treatment and related services increases. Hospitals, already under pressure with staffing shortages, may find themselves needing to increase qualified staff.

Facilities may face financial pressure by virtue of the Institutions for Mental Disease (IMD) Exclusion, which prohibits federal reimbursement for Medicaid patients in residential facilities treating mental diseases, including substance use disorders, that have 16 beds or more in the facility. The result of the IMD exclusion has been that many patients delay seeking treatment and end up using hospital emergency rooms for treatment as a last resort. Various federal proposals have been considered to relax, remove, or modify the IMD prohibition for opioid addiction/treatment.

Physician practices also are experiencing a myriad of legal issues as the front line in dealing with pain medication usage and a source of perpetuating the opioid epidemic with invalid, or unnecessary, pain prescriptions. The government continues its investigation into pill mills with the help of the DOJ's newly established Opioid Fraud and Abuse Detection Unit that is using data analytics to identify over-prescribers.[56]

The large number of deaths from opioid abuse and related causes has created problems for morgues and medical examiner offices. Laboratories and morgues have increased demands while experiencing staffing shortages and a potential lack of compliance with state and local morgue and laboratory requirements.[57]

Pharmaceutical companies and pharmacies may have the most uncertain legal issues stemming from the opioid epidemic. A majority of states are investigating opioid pharmaceutical manufacturers, with a multitude of cities and counties either in pre-litigation or active litigation against the same defendants.[58] Government actors are employing a similar litigation strategy to the initial steps used in fighting tobacco companies. Additionally, pharmacies are now in a similar position to hospitals and physician offices in that they need to monitor pain medication seekers, as well as over-prescribers. Insurers also have started to respond by refusing to cover certain highly addictive pain medication or limiting the number of opioids prescribers can administer to first time users. Such coverage actions may be grounds for future legal issues among pharmaceutical companies, pharmacy benefit managers, and payers.

The FDA also has taken steps to curb the opioid epidemic by demanding that an opioid be pulled from the market due to public health consequences and increasing access to medication-assisted treatment options by approving new drug formulations and devices.

In fiscal year 2017, HHS invested almost $900 million in opioid-specific funding, including to support state and local governments and civil society groups, to support treatment and recovery services, to target availability of overdose-reversing drugs, and to train first responders.[59] HHS announced in September 2017 that it was awarding an additional $144.1 million in federal grants to prevent and treat opioid addiction that was authorized by the Comprehensive Addiction & Recovery Act. In the fall of 2017, the Trump administration declared the opioid crisis a "public health emergency" and the White House's Opioid Commission released their final report making recommendations to help

combat this crisis. Declaring the opioid crisis a public health emergency allows HHS to accelerate temporary appointments of specialized personnel to address the emergency (pending any funding needed); work with the Drug Enforcement Administration (DEA) to expand access for certain groups of patients to telemedicine for treating addiction; and provide new flexibilities within HIV/AIDS programs. However, declaring a public health emergency did not provide the immediate additional funding to combat opioid abuse that declaring a national emergency would have allowed. The administration unveiled a five-point opioid strategy to: improve access to prevention, treatment, and recovery support services; target the availability and distribution of overdose-reversing drugs; strengthen public health data reporting and collection; support cutting-edge research on addiction and pain; and advance the practice of pain management.

States are using various legislative and administrative efforts to fight the opioid epidemic. Some states have enacted legislation allowing naloxone access without a prescription. Ohio has enacted a community-based overdose education and naloxone distribution program called Project DAWN.[60] Community efforts like Project DAWN represent opportunities for health care providers to work with their communities to combat opioid abuse. West Virginia, hit particularly hard by the opioid crisis, has applied for a Medicaid waiver to address substance abuse[61] and is using $24 million from a settlement with opioid distributors to expand the availability of addiction treatment.[62] State responses also include legislative efforts to limit the type of prescriptions that can lead to opioid abuse, requiring reporting by pharmacies, and potentially requiring additional steps (including checking the prescription drug monitoring program) before allowing prescriptions of opioids and related drugs.[63]

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Telemedicine and Digital Health

—Nathaniel Lacktman, Foley & Lardner LLP

The most activity and progress for coverage of telehealth services in 2017 has been at the state level, with approximately 36 states and the District of Columbia having telehealth commercial insurance coverage laws.[64] Under these laws, a health plan must cover services provided via telehealth to the same extent the plan already covers the services if provided through an in-person visit. The laws do not mandate the health plan provide entirely new service lines or specialties, and the scope of services in the enrollee's member benefit package remains unchanged. A subset of states includes payment parity language in their telehealth commercial insurance coverage laws. Telehealth payment parity is different from coverage in that it enables providers for telehealth services to be reimbursed at the same or equivalent rate the health plan pays the provider when the service is provided in-person.

On the Medicare side, telemedicine providers celebrated another successful year of growth, as CMS reported a 28% increase over total payments for telehealth services under the Medicare program compared to last year.[65] In addition, effective January 1, 2018, CMS added seven new codes as covered telehealth services, including psychotherapy, care planning for chronic care management, and health risk assessment.[66] CMS also eliminated the use of the –GT modifier to designate the service was delivered via telehealth, instead replacing it with the simpler "02" Place of Service code. Perhaps the most interesting Medicare coverage change for 2018 is that CMS will reimburse for remote patient monitoring (RPM) services (via its decision to unbundle CPT code 99091), so providers should look to that as another revenue opportunity in the coming year. At least a half-dozen bills remain pending in Congress, any one of which would significantly expand Medicare coverage of telehealth services if signed into law.

On the Medicaid side, 48 states and the District of Columbia provide reimbursement for some form of telemedicine services, most commonly real-time audio-video.[67] Among those states, 15 reimburse for store and forward services and 21 states reimburse for remote patient monitoring. Yet, nearly half of the state Medicaid programs still limit coverage to when the patient is located in a facility or practitioner's office, and do not reimburse when the patient is at his home.

Licensing and Interstate Medical Practice. Last summer, Texas finally enacted a new law to eliminate its notable barriers to practicing via telemedicine, effectively ending a multi-year antitrust lawsuit between Teladoc and the Texas Medical Board.[68] As we enter 2018, physicians can now create a valid doctor-patient relationship via telemedicine in all 50 states (although states continue to maintain variances and nuances on required technology, consent, and practice standards for telemedicine). On the licensure front, nine medical boards offer telemedicine special limited licenses, a decrease from 11 last year.[69] In addition, the Federation of State Medical Boards' Physician Licensure Compact is now live and underway, with 22 states currently participating.[70] The Compact is essentially a clearinghouse for single-point licensure applications in multiple states, and participating state medical boards each retain their licensing and disciplinary authority. It is a step in the right direction, but most telemedicine advocates would have preferred a more streamlined reciprocal arrangement. Finally, Congress is using its federal supremacy powers in a bill that would allow doctors in the Veterans Administration (VA) to deliver telemedicine services to VA patients, without regard for state licensure or the patient's location.[71] The bill passed the House in November and is expected to pass the Senate as well.

Telemedicine Prescribing and Controlled Substances. After creating a valid doctor-patient relationship, telemedicine-based prescribing is widely permitted among the states, although a number of states require the use of real-time audio-video before issuing a prescription. This is changing, and states are beginning to embrace store and forward telemedicine prescribing, which is distinguishable from the problematic and unpermitted

"internet prescribing" or "form-based prescribing" prevalent in the early 2000s. 2018 will see a greater push by providers to use store and forward telemedicine, if only due to the sheer convenience it offers patients coupled with the increasing comfort level among physicians. Ultimately, most states hold that issuing a prescription, whether via telemedicine or otherwise, is up to the professional discretion of the physician and remains subject to the same standard of care as in-person services.

With regard to telemedicine prescribing of controlled substances, the landscape is less favorable. The Ryan Haight Act (Act) remains an obstacle to legitimate prescribing practices.[72] The Act requires a physician to conduct at least one in-person medical evaluation of the patient before prescribing any controlled substances. Once the prescribing practitioner conducts an in-person exam, the regulations do not set an expiration period or a minimum requirement for subsequent annual re-examinations. A number of states allow telemedicine prescribing of controlled substances, but the federal Act preempts state law. The DEA's regulatory calendar had a proposed rule slated for publication in January 2017 to allow for a special telemedicine registration and an exemption from this in-person exam requirement. However, the DEA has not published the proposed rule or released any formal public comment. This has come to a head in connection with the huge potential of telemedicine-based substance abuse treatments to address the opioid crisis in rural areas. Even after the President declared the opioid crisis a public health emergency on October 26, 2017 and issued a recommendation for telemedicine prescribing to trigger an exception to the Ryan Haight Act, the DEA still has not taken concurring action.[73] This will be a red hot issue in 2018.

Emergency Preparedness

—Martha Karam, Rogaliner Law Firm

In 2017, the United States endured 15 natural disasters that each cost $1 billion or more and claimed over 300 lives.[74] State governors issued over 130 emergency declarations, and the President issued three separate emergency declarations for Hurricanes Maria, Irma, and Harvey, all later deemed public health emergencies by then-HHS Secretary Tom Price.[75] While states still are addressing the legal and public health issues that followed these disasters, many speculate that the onslaught of natural disasters shows no signs of slowing down.

Following the death of 14 people in a South Florida nursing home after Hurricane Irma, Governor Rick Scott issued an emergency rule requiring nursing homes and assisted living facilities to install generators. Though an administrative law judge initially threw out the emergency rule, the Governor appealed and the Florida First District Court of Appeal upheld the rule.[76] Meanwhile, Florida lawmakers have proposed similar legislation that would require nursing homes to have alternate power sources installed and the state to prioritize power restoration to elder care facilities during natural disasters. As of mid-November 2017, more than a dozen different bills addressing power sources, access during emergencies, and related safeguards had been proposed to the Florida legislature. The Florida Health Care Association (FHCA) issued a news release noting that it recommended some of the proposals, but opposed other changes for the practical effect they may have on facilities' responsibility to acquire liability insurance.[77] In a similar push for legislation in response to natural disasters, California lawmakers are proposing bills to prevent public utilities from passing on uninsured damage costs to consumers. The legislation is prompted by utilities' ongoing efforts to recover costs in wildfires not covered by insurance by passing them along to ratepayers.

Natural disasters and emergencies similar to the recent hurricanes and fires led CMS to establish a new emergency preparedness rule for facilities that participate in Medicare and Medicaid.[78] The rule attempts to establish consistent emergency preparedness requirements for health care providers participating in Medicare and Medicaid. The new rule, which took effect November 16, 2017, requires health care providers across 17 settings to develop and maintain policies and procedures, communication plans, and training and testing. Under the rule, nursing homes, such as the one in Florida where residents perished during Hurricane Irma, must have alternative sources of energy capable of maintaining safe temperatures. In response to the final rule on emergency preparedness, The Joint Commission also updated its guidelines for emergency management across several health care settings. The updates include 21 new or revised elements of performance for hospitals and critical access hospitals, 29 for ambulatory surgery centers, and 39 for home health agencies.

Other public health concerns followed the recent hurricanes' path and are sure to continue into 2018. In Texas and Louisiana, officials have concerns that the heavy flood waters may lead to water contamination from oil, gas, and chemical operations in the area as well as increased incidences of mosquito-carried illness such as chikungunya, dengue, West Nile virus, and Zika virus. In addition to creating new health problems and injuries, many people with existing conditions are facing issues with access to medications that may have been damaged or lost, and treatment at hospitals and dialysis centers that may have been temporarily closed following the storms. Longer-term public health problems include exposures to molds and mildews triggering illness, similar to the increases seen following Hurricane Katrina.[79]

During the hurricanes, many hospitals and treatment centers were forced to temporarily close or prioritize available services. Now, hospitals may be feeling the financial strain of caring for patients who could not afford treatment and postponing more lucrative surgeries and procedures.[80] On an individual level, many may be facing unexpected medical bills as well as increased insurance premiums in the next year that may take a backseat to paying for home and car repairs and replacements. These issues are sure to be focal points for states struggling to assure their health care facilities are ready to address emergency conditions in 2018. C

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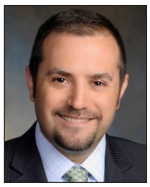

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Internal Investigation of Drug Diversion: An Advanced Compliance Topic

By Heidi Crosby and Cynthia Wisner, Trinity Health

Opioid abuse has reached epidemic levels across the United States and become a driver for drug diversion. Drug diversion is generally defined as the transfer of drugs by theft to an individual to whom they were not prescribed. Opioids are narcotic pain medicines that come in a variety of forms: pill/tablet; transdermal patch; a liquid for infusion via drips; and patient controlled analgesia (PCA) syringes or cartridges. All of these forms are susceptible to diversion. There are also many hand-off opportunities for opioids from the facility's point of entry to the bedside that can complicate diversion investigations. For those involved in health care compliance and providing legal support, conducting a drug diversion investigation is an advanced topic due to the portability of, and level of access to, narcotics within a health care facility, the number of data points that must be reviewed to confirm whether diversion is occurring, the possibility of harm to patients, and the need for an interdisciplinary team of health care professionals to review and resolve a potential diversion matter.

Scenario

Consider the following scenario: a complaint has been made through the UR Community Hospital Compliance Hotline that a staff ICU nurse, "Nurse Amy," has been stealing narcotics. Human Resources (HR) already has suspended Nurse Amy based on this complaint and alerted the patient safety team, which is tasked with reviewing immediate patient safety concerns. Community Hospital's legal team and the Hospital's Compliance Officer have been asked to investigate potential drug diversion and to determine whether a theft or loss of drugs has occurred. The following steps can be taken for the investigation of potential drug diversion.

Initial Response

The first step in the investigation is for the Compliance Officer to review the hotline report to see what additional facts are listed and to develop an investigation plan.

Establish/Activate the Drug Diversion Investigation Team (DDIT)

The Compliance Officer also should consider activating a drug diversion investigation team (DDIT). The DDIT should ideally be established in advance of the need for an investigation and be ready to start the process with defined roles and responsibilities. Each member of the DDIT contributes technical expertise and knowledge of UR Community Hospital operations. Composition of a drug diversion investigation team should, at minimum, include representatives from the following functions within the Hospital: HR; Legal Counsel; Internal Audit/Compliance; Pharmacy; Information Technology; Clinical/Nursing; and Security.

A DDIT lead must be appointed at the initial meeting to establish ground rules and protocols for the investigation. The investigation should be confidential and all communications about the investigation should be limited to members of the DDIT. The lead will coordinate the investigative activities. The Internal Audit or Compliance representatives may be well-suited to this task, as these functions typically have experience managing complex investigations. The DDIT should set a timeline for review of materials/reports and a meeting schedule to review current status/findings. The first action of the DDIT will be to review the hotline report. Consider a limited initial timeframe to be investigated. Typically, three months of activity should be sufficient to ascertain whether diversion is occurring.

Here are some recommended steps for the DDIT to consider in this scenario:

- Suspend Nurse Amy's access to information technology networks and applications, including email;
- Brainstorm possible scenarios of how Nurse Amy could divert narcotics; considering that Nurse Amy may not be acting alone—brainstorm who else may be aware of the alleged wrongdoing or actively participating in any alleged wrongdoing;
- Identify all places where Nurse Amy has access to drugs;
- Obtain security video if video cameras are in operation where drugs are stored or dispensed, noting this request can be time-sensitive as security may only maintain video footage for a limited time;
- Obtain reports from the Hospital's electronic medical record, drug dispensing system, pharmacy records, or other sources to indicate access to and dispensing of drugs by Nurse Amy;
- Obtain Nurse Amy's attendance records, indicating days worked including start and end times;
- Obtain security card/badge access reports to determine whether Nurse Amy is accessing secure locations outside of her work hours;
- Consider what technology is specifically assigned to or accessed by Nurse Amy (i.e., email, computer, cell phone) as these may need to be sequestered for review; and
- Investigate the potential for circumvention of the controls (automated or manual) over the drugs Nurse Amy may be able to access.

HR would take the lead on investigating whether Nurse Amy might have been impaired at work prior to being suspended.

Indications of Diversion

Investigators will be equipped to ask questions and gather information with knowledge of potential early signs that an individual is using or selling drugs, such as:

- Long periods of time between pulling medication and administration;
- Wasting of whole doses or delayed wasting;
- Inconsistencies in patient pain scores over several shifts;
- Increase in certain medication usage on the unit not consistent with census or patient acuity;
- Changes in Nurse Amy's work performance, attitude, attire, attendance, relationships (personal and work);
- Changes in Nurse Amy's financial situation (recently better or worse); and/or
- A triggering event in Nurse Amy's life: a recent death, illness, loss of household income, etc.[1]

Information Gathering

The following is a sample of reports that may be meaningful in the investigation. The DDIT should gather as many of the following as possible and relevant for the timeframe under investigation based on the theories established:

- Time and attendance reports;
- Badge reader reports;
- Bedside medication bar code scanning input data;
- Electronic medical record reports indicating medication administration, pain scores, etc.;
- Medication inventory reconciliations;
- Patient complaints;
- Automated dispensing technology reports;
- Medication wasting reports; and
- Recent relevant audit reports or investigations.

The Investigation

Each possible scenario may necessitate a different investigative approach. The DDIT should consider the facts of the case as well as viable scenarios/theories. Based on what is known or suspected, the DDIT should consider how each may present in the records/reports available. A trail from the moment Nurse Amy clocks in for her shift to the moment she clocks out should be traced to find patterns: movements through the patient medical records to the medication storage/dispensing and back to the patient or wasting reports. A review of the inventory reconciliation reports for discrepancies also would be appropriate.

A member of the DDIT should conduct a walk-through of Nurse Amy's work areas, especially if a team member is not familiar with the layout and location of medication storage, automated medication dispensing stations, and surveillance devices to note whether a medication can be removed or pocketed without others noticing. A general walk-through to identify areas where Nurse Amy could wander and diversion would be possible could be conducted.

Interview Tips and Techniques

The DDIT should develop a list of individuals to interview, such as co-workers and others who may provide information on medication controls/weaknesses in place at the Hospital. Note that interviews can be sensitive as information could get back to Nurse Amy and alert her to an active investigation. Always start with individuals furthest away from Nurse Amy and narrow the circle until the final interview, which should be Nurse Amy. The DDIT should plan the interview schedule thoroughly and consider the following when developing a plan:

- Have two members of the team in each interview—one lead interviewer and one note-taker. This will allow the interviewer to focus on asking the questions and monitoring the non-verbal cues of the witness and allow the note-taker to create a thorough record of the discussion. This also may protect against a false accusation of harassment.
- Interview only one individual at a time so that interviewees are not able to hear the questions in advance or align their statements and so that one interviewee does not dominate or intimidate the other.
- Be aware of the interview room layout. Consider removing furniture that could block the view of the interviewee's body language and non-verbal cues or block the interviewee's ability to exit the room freely.

Continued on page 34

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- When beginning the interview, start with normalizing questions to observe the interviewee's standard responses in comparison to responses to more difficult questions asked later in the meeting.
- Prepare a list of interview questions and ask questions even if the DDIT thinks it knows the answer.
- Ask probing questions to determine how someone might divert medication and what controls are in place to prevent that from happening.
- Ask whether the interviewee is aware of or suspects anyone of diverting drugs.
- As much as possible, make the interview conversational not confrontational.
- Discuss the confidentiality of the interview and request that the interviewee keep the interview confidential—consistent with applicable labor laws.
- Provide contact information should the interviewee remember additional relevant information after the interview.

Reporting

As noted above, upon receiving notice that there is a suspicion of drug diversion, patient safety procedures should be initiated, including review of patients' health statuses and medical records.

Even before the investigation is complete, the Hospital will have to determine whether reports are required. Hospitals typically are not required to submit reports about suspicions or confirmation of inappropriate behavior of their employees. However, Drug Enforcement Administration (DEA) registrants are required to report suspected drug diversions, which include manufacturers, distributers, and dispensers. Pharmacies and hospitals are defined as dispensers by the DEA.[2] As such, the Hospital should notify the DEA field office within one business day of discovery of a suspected loss or theft. DEA Form 106 should be submitted once the circumstances surrounding the theft or significant loss are clear; however, updates should be provided to the DEA if the investigation takes more than two months.[3] Many state laws also require reports to be filed regarding the offending provider with his or her respective licensing board, so a review of other laws that impact the Hospital must be considered. If the investigation reveals that Nurse Amy misused information technology (IT) access or accessed records of patients she was not caring for to obtain narcotics, then these actions should be analyzed under the Health Insurance Portability and Accountability Act/Health Information Technology for Economic and Clinical Health Act breach notification rule.

In addition to the reports required to be filed by the Hospital and Nurse Amy's co-workers, Nurse Amy may have to notify her licensing agency, among others. A recovery program is likely available for Nurse Amy to mitigate the impact on Nurse Amy's license and enable her to return to her profession, depending on the state of licensing.

Routine Monitoring

The DDIT is an integral component of an effective drug diversion detection and prevention program and therefore should not dissolve after the investigation has been completed. The Compliance and IT departments should continue to monitor and share data with the DDIT. As part of an effective compliance program the DDIT should: seek opportunities to educate staff on the warning signs of drug diversion; brainstorm checks and controls to mitigate the likelihood of diversion; periodically review policies and procedures relative to drug diversion and controls; recommend and review audit reports to test the effectiveness of controls; and if unusual activity occurs the DDIT should initiate an investigation.

Conclusion

Receiving a hotline call or complaint alleging the theft of narcotics is a serious matter. Immediate action should be taken to determine if there was an impact on patient safety. Prompt action to investigate and determine whether drugs were diverted, as well as employee education and regular monitoring activities will help establish a culture of compliance that may mitigate the likelihood of future diversions. C

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Cynthia Wisner represents hospitals, health care systems, physician groups, nonprofits, and other health care organizations—graduating from University of Michigan Law School in 1981. She is in-house counsel in the legal department of Trinity Health, one of the largest Catholic health care systems in the United States. She has completed terms on the Board and as Chair of the In-House Counsel Practice Group of the American Health Lawyers Association (AHLA). She also completed a term as the Editor-in-Chief of AHLA's *Journal of Health and Life Sciences Law*, and is a co-editor of the AHLA *Compliance Manual*.

Endnotes

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Maximizing Productivity as a Young Professional

Geneva Campbell Brown, Dechert LLP

One of the most important skills for young lawyers to master is maximizing productivity. Better productivity improves an individual's personal sense of accomplishment as well as the level of trust and admiration received from clients and supervising attorneys. Below are a handful of tips to assist young lawyers who are seeking to become their most productive selves:

1 Maintaining Focus

One of the simplest yet most difficult tasks is remaining focused. When workflow is slow, lethargy may set in, along with the urge to engage in mindless activities like internet browsing. When work is busy, it is easy to waste time feeling disorganized while fielding emails. During times of feast or famine, the first thing to do is set a billable hour goal each day. This time may be filled with a mix of client billable work, pro bono, networking, or training. Setting a target ensures that each day consists of a minimum number of productive hours. Additionally, setting a target guarantees time to monitor news regarding the ever-changing health care laws and regulations. The second thing to do to maintain focus is plan out tasks. Crafting a "to-do list," managing your calendar, and fixing personal deadlines are efficient ways to establish a plan for accomplishing short-term goals.

2 Immediate Billing

The main key to productive billing is to record the work performed. To bill accurately, billing immediately is crucial. Recording time immediately allows young lawyers to assess where they stand in terms of their billable hours requirement or time spent on specific projects, which is especially important for health care clients that request billing statements on demand. Recording time immediately also ensures time is not wasted struggling to recall tasks or under-billed because you are forced to estimate. The health care industry has embraced business models that promote more efficient payment and care delivery, which has triggered requirements that in-house and outside legal counsel work diligently to keep costs down.

3 Working Remotely

When used wisely, remote access to employer technologies is extremely useful. Establishing a secondary workplace affords the ability to work from the office without sacrificing quality or efficacy and offers the flexibility to leave the office for personal activities knowing that, if work arises, such work can be completed proficiently. Working remotely is particularly important in the current health care climate where clients use telemedicine and other technologies, and expect their attorneys to be adept at shifting conversations from physical to virtual.

4 Delegating Efficiently

Delegation benefits young lawyers because assigning projects to trustworthy junior attorneys and staff permits concentrating on more complex projects, building increasingly advanced knowledge and skills, and contributing to projects on a strategic level. Developing a broader skill set and knowledge base is particularly important for health care lawyers who seek to be in demand through the possession of familiarity with specialized compliance or legal issues, particularly those that involve newly enacted health laws and regulations (for which there are many).

5 Ask to be Productive

Many supervising attorneys value associates who are productive. Young professionals should seek feedback regarding whether their practices and habits are viewed as reflecting a maximum level of productivity. Susan Hendrickson, health care partner at Dechert LLP, states that in order to be seen as productive, ask to produce work: "You would be surprised how positively colleagues and clients respond if you ask for feedback on your level of productivity, ask for opportunities to take on additional work, or ask for the responsibility of delegating to junior lawyers. As a partner, I may not always have enough bandwidth to consider each associate's development, so I am grateful for 'the ask.'" Asking to be productive provides otherwise unavailable opportunities for development of skill sets and a knowledge base in the health care industry where laws and technologies are constantly changing.

Arizona

Scottsdale, AZ: Assistant General Counsel, HonorHealth. HonorHealth is a nonprofit health system serving an area of 1.6 million people in the greater Phoenix, Arizona area. The network encompasses five acute care hospitals, an extensive medical group, outpatient surgery centers, a cancer center, clinical research, medical education, two foundations, and community services. Responsible for advising on a wide variety of legal matters, including contracts, affiliations, leases, medical staff matters, and fraud/abuse analysis. JD with four years' health care experience, registered as an attorney with the Supreme Court of Arizona and be licensed to appear and practice in all courts and agencies in the State of Arizona or licensed to practice in another state and registered and licensed in Arizona within 12 months of hire. Exceptional benefits, including Health, Dental, Vision, and Pet Insurance, Tuition Reimbursement, 403(b), 529, Child Care Center, In-Home Sick Child Care, and much more. Email resume to Thomas.Licari@HonorHealth.com or call 602-448-1610. EOE

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Orange, CA: Associate General Counsel, Children's Hospital of Orange County. The Associate General Counsel reports to the Chief Legal Officer and assists the Chief Legal Officer with providing strategic direction and leadership for all legal services needed for Children's Hospital of Orange County and its affiliates. The Associate General Counsel works collaboratively with departments throughout the organization to meet their legal needs and provide legal support on projects. The Associate General Counsel may also independently manage a portfolio of legal matters relating to physician agreements, high risk and/or high value contracts, litigation, managed care, and regulatory compliance, among other issues. The Associate General Counsel will train and supervise legal department staff to accomplish department goals and improve the quality of service to all customers. Minimum of five years of experience in the practice of law in a health care organization and/or a law firm dealing with issues such as health care laws, corporate compliance, large services contracts, employment issues, etc. Must have knowledge of health care provider standards and regulatory issues, including Stark, Fraud and Abuse, HIPAA, and HITECH. Management experience is required. To apply for this position, please visit the AHLA Career Center at www.healthlawyers.org. On the top navigation bar, click on "Find a Resource," then select "Career Center."

Sacramento, CA: Associate/Of Counsel, Salem & Green. Salem & Green, A Professional Corporation, is a boutique law firm in Sacramento, California that specializes in health care (business and regulatory), mergers and acquisitions/dispositions, and securities. See our website at www.salemgreen.com for additional information about our firm. The ideal candidate will be licensed to practice in California and have practiced in one or more of the following areas for at least one year: health care regulatory (familiarity with health care regulatory issues, such as Stark, fraud and abuse, reimbursement related issues, licensing, and enrollment) would be a plus, but not a requirement; and/or transactional business law (mergers and acquisitions/dispositions, securities, tax, or other business transactions). Compensation Negotiable. Salary/bonus commensurate with experience and billable hours. Please apply to Jobs@salemgreen.com with salary requirements.

San Diego, CA: Risk Manager, Rady Children's Hospital. Rady Children's Hospital, San Diego, is the premier pediatric provider in the region with 551 beds, a medical practice foundation, multiple Southern California satellite locations, and a full range of progressive and innovative clinical, teaching, and research programs. Rare opportunity to combine your health care operational experience and legal knowledge and skills as a key member of the Rady Children's Hospital and Health Center Legal Department. Successful candidates will have exceptional analytical, problem-solving, and communication skills, knowledge of health care risk management, claims management processes, related health care law, and the hospital regulatory framework. The ability to evaluate clinical issues for risk

exposure and problem-solve patient care and other operational matters is needed. Minimum Qualifications: Juris Doctorate Degree (JD); three years of related experience; California Bar licensure or out-of-state license to practice law with the ability to register as an in-house counsel in California. To apply for this position, please visit the AHLA Career Center at www.healthlawyers.org. On the top navigation bar, click on "Find a Resource," then select "Career Center."

Colorado

Englewood, CO: Corporate Counsel, Catholic Health Initiatives. Corporate Counsel position with Catholic Health Initiatives at our national office in Englewood, Colorado. Position is primarily focused on Labor and Employment, and health care experience is preferred. Please visit www.catholichealthinit.org to apply online to requisition 2017-R013854.

Connecticut

Hartford, CT: Health Law Associate, Robinson & Cole. Robinson & Cole LLP, an Am Law 200 firm, seeks an attorney to join its Health Law Practice Group in Hartford, CT; Stamford, CT; Boston, MA; Providence, RI; or New York, NY. Qualified candidates will have at least five years of experience advising health care providers on transactional and regulatory health law issues. In addition, qualified candidates must have excellent written, verbal, analytical, and interpersonal skills, as well as superior academic credentials. For the right candidate, this position may be situated in Hartford, Stamford, Boston, Providence, or New York, with Hartford being the preferred location. Admission to the bar for the State where the Associate sits is required. Top academic credentials, excellent writing, research, negotiation, and communication skills also required. For consideration, please send cover letter, resume, writing sample (preferably not edited by others), and law school transcript to: Lisa M. Vooys Recruiting, Development & Paralegal Manager, Robinson & Cole LLP, 280 Trumbull Street, Hartford, CT, 06103; attorneycareers@rc.com.

Stamford, CT: Health Law Associate, Robinson & Cole. Refer to listing under Hartford, CT for a full description.

District of Columbia

Washington, DC: Senior Vice President, Legal & Advocacy, 340B Health. 340B Health looks forward to meeting with you. To apply for this position, please visit the AHLA Career Center at www.healthlawyers.org. On the top navigation bar, click on "Find a Resource," then select "Career Center."

Washington, DC: Director of Corporate Affairs/Board Secretary, Children's National Health System. As one of the nation's top ten children's hospitals, according to *U.S. News and World Report*, Children's National Health System is undergoing an exciting period of transformational growth. We're seeking a dedicated professional with a genuine advocacy for the mission of the organization and the many children and families who benefit from the care and comfort they provide. If you're a leader who is insightful and politically and culturally astute, we'd like to talk to you about overseeing the conduct of corporate board affairs within the Children's National Health system. You will serve as staff to all corporate boards and advise and assist the President and other management staff on compliance and application of governance policies and timetables. Your guidance will help us streamline Board communication and ensure efficient and effective use of board leadership's time and expertise. Send your resume to whays@childrensnational.org or apply online at https://cnhs.taleo.net/careersection/jobdetail.ftl?job=170002VH&lang=en#.Wg7kGF8epd8.

Washington, DC: Health Care Disputes Lawyer, Norton Rose Fulbright. Norton Rose Fulbright seeks a part-time/flexible work schedule Health Care Disputes lawyer. To apply for this position, please visit the AHLA Career Center at www.healthlawyers.org. On the top navigation bar, click on "Find a Resource," then select "Career Center."

Washington, DC: Health Care Attorney, Thompson Coburn LLP. Refer to listing under Chicago, IL for a full description.

Florida

Rockledge, FL: Senior Counsel–Corporate Legal Department, Health First Health Plans. To be fully engaged in providing Quality/No Harm, Customer Experience, and Stewardship by providing legal counsel and support to Health First, Inc. and its affiliated entities. The Senior Counsel is responsible for providing superior quality, competitive value, and outstanding service by giving legal support and assistance to the legal department, medical staff leadership, health plan, and hospital executives. Juris Doctorate degree; Member of the Florida Bar preferred and may be required, Florida Bar Board Certification in Health Law preferred; Demonstrated experience in contract review and drafting required; Proficient in public speaking, conflict resolution, and problem solving; Minimum of five years' legal experience in health care related field and/or compliance or regulatory programs; Three to five years of supervisory experience preferred; Proficient in Microsoft Office and other software as needed; Demonstrated knowledge of health care risk management statutes and rules preferred; Health Care Compliance experience and/or certification preferred, Demonstrated experience with regulations relating to Florida Agency for Health Care Administration, Medicaid, and Medicare preferred. To apply for this position, please visit the AHLA Career Center at www.healthlawyers.org. On the top navigation bar, click on "Find a Resource," then select "Career Center."

Illinois

Chicago, IL: Health Care Attorney, Thompson Coburn LLP. Thompson Coburn LLP's corporate health care practice area seeks a Health Care Attorney with at least five to seven years of experience handling regulatory and corporate transactional matters in the health care industry to join its St. Louis, Chicago, or Washington, DC offices. Law firm experience and in-depth understanding of Fraud and Abuse, Stark, Medicare reimbursement, hospital physician relationships, provider-payer relationships, and HIPAA also required. The position offers the opportunity to work on a wide variety of corporate transactions and regulatory matters for health care organizations, including health care systems, hospitals, health insurance companies, long term care providers, physician practices, and other health care related businesses. To apply for the position, go to https://www.thompsoncoburn.com/careers to submit

a cover letter, resume, transcripts, and writing sample. Applications will not be accepted by email.

Rockford, IL: Staff Attorney, Mercyhealth. We seek a talented individual to join us as a Staff Attorney for Mercy Health Corporation, our wholly-owned parent company, which links Mercyhealth together by offering a complete continuum of health care services to our membership, including seniors, individuals, and area employers and their employees. Under the guidance of the Vice President of Legal Affairs-General Counsel and Assistant General Counsel for Corporate Law Matters, the professional we select for this vital role will provide timely and exceptional legal services to Mercyhealth and its affiliates, with a strong focus on the areas of regulatory and contract law. In addition to opportunities to learn, grow, and advance, Mercyhealth offers health and dental insurance, vacation, matched retirement savings, and more. Apply online at www.mercyHealthSystem.org.

Zion, IL: Director Compliance & Privacy, Cancer Treatment Centers of America. Refer to listing under Tulsa, OK, for a full description.

Indiana

Carmel, IN: Senior Attorney, Ascension Health. Ascension Health seeks a Senior Attorney in Carmel, Indiana. The Senior Attorney serves as a legal advisor for ministry markets within an assigned region, providing direction, guidance, and assistance on legal matters. Responsibilities include overseeing and managing outside counsel, supporting governance activities for the ministry markets within the assigned region, advancing the implementation of policies and procedures in the ministry markets, and collaborating with legal practice area team leads. Juris Doctorate and ten years as a licensed practicing attorney required. Multi-site health systems or hospital systems experience preferred. Apply online: http://bit.ly/2Alrp4k.

Indianapolis, IN: Legal Counsel Sr., Associate General Counsel, or Associate General Counsel Sr., Anthem, Inc. This is an exceptional opportunity to do innovative work that means more to you and those we serve at one of America's leading health benefits companies and a Fortune Top 50 Company. Preferred location: California, but open to other Anthem locations. Provide legal support to the Grievances and Appeals Department regarding the resolution of disputes from members and providers and work on mitigating the regulatory and litigation risks arising from those disputes. Regularly interact with state regulators in connection with member grievances and provider disputes, including, in particular, in California. Provide legal advice to business partners regarding G&A processes and the implementation of related enterprise-level and state-specific initiatives. Assist with the resolution of grievances sent to Anthem leadership. Participate in meetings with customers, including employer groups, regarding G&A issues. Requires a JD; current license to practice law; 15 years of specific industry and/or technical legal experience post licensure, including experience in managing outside counsel; or any combination of education and experience that would provide an equivalent background. To apply for this position, please visit the AHLA Career Center at www.healthlawyers.org. On the top navigation bar, click on "Find a Resource," then select "Career Center."

Maryland

Baltimore, MD: Associate Senior Counsel, The Johns Hopkins Health System Corporation. The Johns Hopkins Health System Corporation Legal Department seeks an attorney to support supply chain/procurement activities, including our internal supply chain group and commercial group purchasing organization. Responsibilities include providing general advice to both business teams, drafting and negotiating a broad range of vendor and supplier transactions, including medical equipment and maintenance agreements, product purchase agreements, including the purchase of pharmaceutical drugs and supplies, and service agreements. Ability to be proactive and a problem solver who can handle a large workload and who has strong interpersonal skills and integrity. Experience in a health care setting or group purchasing organization and familiarity with anti-kickback and fraud and abuse statutes is preferable. Five to ten years of experience as a practicing attorney, licensed and a member of the Maryland or other state Bar, required. Only applicants invited for an interview will be contacted. Please send your resume to cmcente2@jhmi.edu.

Windsor Mills, MD: Deputy Center Director, Centers for Medicare and Medicaid Services. Become a part of the Department that touches the lives of every American! At the Department of Health and Human Services, you can give back to your community, state, and country by making a difference in the lives of Americans everywhere. Join HHS and help to make our world healthier, safer, and better for all Americans. The Centers for Medicare and Medicaid Services (CMS) works in partnership with the entire health care community to improve quality and efficiency in an evolving health care system and provides leadership in the broader health care marketplace. Our effectiveness depends on the capabilities of a dedicated professional staff that is committed to supporting these objectives. A career with CMS offers the opportunity to get involved on important national health care issues and be part of a dynamic, fast-paced, and highly visible organization. Visit https://cms.usajobs.gov/ for more exciting opportunities!

Massachusetts

Boston, MA: Health Care Attorney, Sheehan Phinney. Sheehan Phinney is a 60-attorney, full service regional law firm with offices in Boston and New Hampshire. It seeks a Health Care Attorney with portables, eight plus years' experience, and fluency in all relevant federal laws and regulations, including Stark, Anti-Kickback, HIPAA, etc., to join a sophisticated health care practice in our Boston office. To apply for this position, please visit the AHLA Career Center at www.healthlawyers.org. On the top navigation bar, click on "Find a Resource," then select "Career Center."

Boston, MA: Health Law Associate, Robinson & Cole. Refer to listing under Hartford, CT for a full description.

Worcester, MA: Assistant General Counsel; UMass Health Care. We seek a health care attorney, an Assistant General Counsel, to join our Legal Department, primarily in the Employment Group. We are looking for a lawyer who possesses the ability to deliver proactive, high-quality client service. The candidate should have a minimum of three years of experience working in, or for, health care clients, focused on matters of health law. Knowledge of federal and state health care laws (including privacy, peer review, Stark,

fraud and abuse, and regulatory compliance matters) and familiarity with legal issues related to patient care and medical staff are preferred. We are looking for a colleague with outstanding relevant legal experience, excellent interpersonal skills, a commitment to client satisfaction, and a desire to be part of a great team. Candidates, please apply online at www.umassmemorial.org. We embrace diversity in both our workforce and our approach to patient care. An Affirmative Action/Equal Opportunity Employer.

Michigan

Detroit, MI: Corporate Counsel, Henry Ford Health System. This individual will be a member of the Office of General Counsel and will be responsible for the development, and efficient utilization of, IT legal support resources, and for the collaboration between the Office of General Counsel and the Information Technology Division. Duties include IT contract review, licensing guidance to IT decision makers, and eDiscovery analytics. Will also provide legal and subject matter expert guidance for electronic systems and platform to support the Office of General Counsel and its constituent functions. Also responsible for project management and IT contract consolidation initiatives, which require collaboration between Office of General Counsel and the IT division. This person is responsible for promoting the lawful use of technology, implementation of legal technology solutions to support transactions, litigation, and electronic eDiscovery efforts for IT-related contracts. These technology tools and systems would facilitate productivity by enabling efficient, cost-effective, and compliant IT and legal departmental processes. To apply for this position, please visit the AHLA Career Center at www.healthlawyers.org. On the top navigation bar, click on "Find a Resource," then select "Career Center."

Minnesota

Saint Paul, MN: Nursing Practice and Regulatory Affairs Specialist, Minnesota Nurses Association. Minnesota Nurses Association is hiring a full-time Nursing Practice and Regulatory Affairs Specialist. Seeking Union-aware RN with Master's Degree plus experience with regulatory issues and public policy. Very visible and interconnected position, responsible for policy, regulatory, and statutory analysis with cross-functional teams to achieve strategic goals of the MNA. We are 20,000 dedicated RN's and other health care professionals in Minnesota, Wisconsin, and Iowa who promote the professional, economic, and personal well-being of nurses through collective action. To apply, send cover letter and resume to Teresa Mazzitelli at tm@mazz-search.com.

Missouri

St. Louis, MO: Health Care Attorney, Thompson Coburn LLP. Refer to listing under Chicago, IL for a full description.

Springfield, MO: Executive Director Counsel, Mercy Hospital. The ED, Counsel provides front line legal counsel and subject matter expertise, in multiple complex areas, to Mercy leadership for operations in western Missouri and Kansas. Working with diverse client teams to review, interpret, and provide implementation guidance on federal and state regulations, such as the False Claims Act, Anti-Kickback Statute, and Stark Law; Juris Doctor (JD) and Bar Admission in Missouri; Eight plus years' legal experience in health care, representing hospitals and physician clinics, and corporate and nonprofit law; A high level of sophisticated legal judgment and leadership ability, to assist in guiding projects, along with the ability to identify, analyze, and develop strategy for areas of legal need; Advanced interpersonal and communication skills; The analytical skills to resolve highly complex problems requiring the application of scientific or technical principles, theories, and concepts and in-depth, experienced-based cross functional knowledge. To apply for this position, please visit the AHLA Career Center at www.healthlawyers.org. On the top navigation bar, click on "Find a Resource," then select "Career Center."

New Jersey

West Orange, NJ: Generalist/Contracting Attorney, RWJBarnabas Health. The RWJBarnabas Health Legal Department has another exciting growth position for a self-motivated individual to join our growing System and Legal Department. RWJ Barnabas Health is a growing diverse and sophisticated health care organization with 13 hospitals, multiple outpatient facilities and joint ventures, and over 1,000 employed physicians. Contract-related legal services to support this growth are a core function of the Legal Department. The Generalist Contracting Attorney will provide legal guidance and support on contracts and contract-related transactions in multiple disciplines from throughout the System. The position will have exposure to a broad range of clients and will report to the General Counsel and the Deputy General Counsel. Minimum of five years of experience at either a top law firm and/or in the legal department of a large organization; Extensive knowledge of applicable state and federal health care laws, rules, and regulations; Experience in a health care related law firm or legal department of a sophisticated health care organization is preferred, but not required. Apply here: https://www.rwjbarnabashealthcareers.org/.

West Orange, NJ: Commercial and Compliance Generalist Attorney, RWJBarnabas Health. RWJ Barnabas Health is the most comprehensive health care system in New Jersey. The successful applicant will: Review, draft, and negotiate commercial, physician, real estate, and other contracts and transactions, including physician employment agreements, leases, physician acquisitions, professional service agreements, and other business arrangements; Provide legal support and guidance with respect to strategic transactions, including preparing and reviewing documents, performing due diligence, and advising on various issues; Provide advice to the Compliance Department, and other clients, with respect to Stark, anti-kickback, federal reimbursement, civil monetary penalty, HIPAA, licensing, EMTALA, and other federal and state regulatory requirements. Qualifications: Juris Doctorate degree from a nationally recognized law school; Active bar membership in at least one U.S. jurisdiction and eligibility for admission to the New Jersey bar as in-house counsel; Minimum of five years of experience at either a top law firm and/or in the legal department of a large organization. To apply for this position, please visit the AHLA Career Center at www.healthlawyers.org. On the top navigation bar, click on "Find a Resource," then select "Career Center."

New Mexico

Albuquerque, NM: SVP - General Counsel, Presbyterian Healthcare Services. Presbyterian Healthcare Services is a locally owned, nonprofit health care system of eight hospitals, a statewide health plan, and a growing multi-specialty medical group. Founded in New Mexico in 1908, it is the state's largest private employer, with approximately 11,000 employees. Reporting directly to the President and CEO and working closely with the Board, the General Counsel is an integral part of the senior leadership team. The General Counsel will be an exceptional health care generalist, expected to develop and maintain the legal capacities of the organization through the oversight of a relatively lean legal department and the evaluation and supervision of all legal resources. S/he will serve as Corporate Secretary for Presbyterian Healthcare Services and related nonprofit organizations, documenting the activities of each governing process and ensuring compliance with corporate and tax law requirements. In addition to the legal function, the General Counsel also oversees Risk and has administrative responsibility over the Compliance function, which has a direct reporting relationship to the Audit Committee of the Board. Requirements: JD from an accredited law school, with a minimum of 15 years of legal experience in a health care setting. AA/EOE/VET/DISABLED. PHS is a drug-free and tobacco-free employer, with smoke free campuses. Apply online: www.phs.org/careers, to requisition 10581.

New York

New York, NY: Health Law Associate, Robinson & Cole. Refer to listing under Hartford, CT for a full description.

North Carolina

Greenville, NC: Assistant/Associate University Attorney, East Carolina University. The East Carolina University (ECU) Office of University Counsel seeks a dynamic Assistant/Associate University Attorney to support expansion of research and health sciences enterprises, research productivity, licensing, and economic development activities at ECU. Position provides legal support to the Divisions of Research, Economic Development, and Engagement (REDE) and Health Sciences (HSD) on research issues and health care transactional matters, including support of Brody School of Medicine and School of Dental Medicine. Position provides professional legal advice and counsel related to REDE and HSD activities and other matters. Minimum requirements: JD ABA-accredited law school; Current member of NC Bar or eligible for admission to NC Bar within one year of hire; Minimum one year experience practicing law or employed with responsibility for regulatory compliance in connection with research administration, sponsored programs, or health care transactions. Please see complete posting for full job description; specific requirements: http://ecu.peopleadmin.com/postings/10743.

Oklahoma

Tulsa, OK: Director Compliance & Privacy, Cancer Treatment Centers of America. Cancer Treatment Centers of America seeks a Director of Compliance and Privacy at three possible locations–Zion, IL; Tulsa, OK; and Philadelphia, PA. The Director is responsible for managing the implementation of CTCA's Ethics and Compliance program at the hospital. The requirements for this role include: Bachelor's Degree in a health-related field required, i.e., RN, RHIA, etc.; Masters of Health Administration, JD or MBA strongly preferred–Certified in Health Care Compliance, CHC, or equivalent required; Five plus years of progressive compliance experience required, with a minimum of three years of health care experience in a hospital setting.

Pennsylvania

Philadelphia, PA: Director Compliance & Privacy, Cancer Treatment Centers of America. Refer to listing under Tulsa, OK for a full description.

Rhode Island

Providence, RI: Health Law Associate, Robinson & Cole. Refer to listing under Hartford, CT for a full description.

Tennessee

Nashville, TN: Managing Counsel–Health Care and Lab Operations, American Addiction Center, Inc. The Managing Counsel–Health Care Contracting and Lab Operations will work independently, under limited direction of the Chief Legal Officer, General Counsel and Secretary of the Company, to oversee and direct government payer participation, health care contracting, and health care regulatory needs of the Company. This is an executive management position, exempt from overtime, and will report to the Corporate Office in Brentwood, TN. The Company is American Addiction Centers, Inc. We are a leading provider of inpatient and outpatient substance abuse treatment services. We treat clients who are struggling with drug addiction, alcohol addiction, and co-occurring mental/behavioral health issues. We currently operate substance abuse treatment facilities, located throughout the United States, focused on delivering effective clinical care and treatment solutions. To apply for this position, please visit the AHLA Career Center at www.healthlawyers.org. On the top navigation bar, click on "Find a Resource," then select "Career Center."

Nashville, TN: Health Care Operations Counsel, Koerner & Associates, Inc. Tennessee-based health care company seeks a health care operational attorney with regulatory/compliance experience. Candidate should have two to eight years of health care or hospital operations experience handling the following: review contracts, medical staff matters, physician practice matters and contracts, fraud and abuse compliance, Stark law and the federal Anti-Kickback statute, HIPAA, EMTALA, Certificate of Need laws, licensing, and Medicare reimbursement. Candidate should have ability to provide day to day health care regulatory advice to CEOs, CFOs, and Boards of Directors for hospitals, physician groups, etc. Strong management and communication skills required. Major law firm or in-house experience preferred. Please send resume in Word format. To apply for this position, please visit the AHLA Career Center at www.healthlawyers.org. On the top navigation bar, click on "Find a Resource," then select "Career Center."

Texas

Houston, TX: Assistant General Counsel –Commercial Contracts, Memorial Hermann Healthcare System. This position serves the organization as legal counsel in one or more of the following areas: labor and employment, IT, insurance and regulatory affairs, clinical operations, and business affairs. Provide substantive legal advice and counsel to a

broad array of both complex and routine organizational legal issues. This position will routinely provide advice and counsel to System leaders on both operational and strategic decisions impacting the organization's success. Position reports directly to the Deputy General Counsel and may supervise legal support staff. To apply for this position, please visit the AHLA Career Center at www.healthlawyers.org. On the top navigation bar, click on "Find a Resource," then select "Career Center."

Virginia

Alexandria, VA: Senior Regulatory Affairs Specialist, American Physical Therapy Association. The American Physical Therapy Association seeks a Senior Regulatory Affairs Specialist in our Alexandria, VA office. This position provides management, implementation, and expertise of regulatory affairs initiatives, compliance issues, and policies from federal agencies. Also provides legal and regulatory perspective and supporting resources in policy development and strategy related to APTA's mission, goals, and objectives. Must have three plus years' regulatory experience. Please send resume to jobs@apta.org.

Richmond, VA: Associate General Counsel –Payer Relations, VCU Health System. VCU Health System's Legal Counsel seeks an Associate General Counsel for Payer Relations. This position is a key team member in the Office of the General Counsel, reporting to the Vice President and General Counsel for VCU Health System. You will be responsible for handling complex legal projects, and one of the main clients for this position will be Virginia Premier, a Medicaid Managed Care Company with approximately 201,890 members. Qualifications: Juris Doctor, or equivalent, from a law school accredited by the American Bar Association; Minimum five years of experience with a law firm or in-house legal department, preferably performing legal services for health systems; Experience navigating complex corporate health care organizations and academic medical centers; Expertise in federal/state/local and agency regulations affecting corporate health care provider operations, health plans, and managed care programs. For details/to apply, visit www.vcuhealth.org/careers and search via Req. # 43644. EOE M/F/D/V.

West Virginia

Morgantown, WV: Vice President and General Counsel, WVU Medicine/West Virginia United Health System. WVU Medicine/West Virginia United Health System has an excellent opportunity for a Vice President and General Counsel (GC). This position will serve as a member of the Senior Leadership team and is responsible for directing the day-to-day legal affairs of West Virginia United Health System (WVUHS), West Virginia University Hospitals (WVUH), WVUH's subsidiary hospitals, and West Virginia University Medical Corporation (WVUMC). To apply, please visit www.wvumedicine.org/careers.

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AHLA

APRIL 19th, **2018**

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AHLA DAY

AHLA Day is an opportunity to **engage** with your colleagues by promoting your involvement in the Association, **share** why you belong and what you gain from your affiliation, and **encourage** your colleagues to join you. AHLA Day includes networking receptions in four cities (Atlanta, Chicago, Nashville, and Washington, DC) and informal post reception dinners, as well as a variety of other networking events around the country.

Visit **www.healthlawyers.org/AHLADay** for more details!

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Showcase your firm's leadership and invest in AHLA Day 2018 today.
Contact Valerie Eshleman at veshleman@healthlawyers.org for more information.

A History of Excellence

Over the previous year, in celebration of AHLA's 50th Anniversary, we have been highlighting key moments in our history of excellence.

Visit **www.healthlawyers.org/AHLA50** to learn more about AHLA's history! An interactive timeline containing photographs, key milestones, and a repository of audio files and transcripts from interviews with the Association's Past Presidents and Fellows has been created and is viewable by all members and the public. We plan to continue to update the timeline with additional photographs, interviews, and transcripts so be sure to check back frequently.

Visit AHLA's YouTube channel at
www.youtube.com/user/healthlawyers
to view the Documentary and video interviews!

2018

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