Health Law Handbook

2025–2026 Edition

Issued in October, 2025

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Thomson Reuters™

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Mat #43278880

ISBN: 978-1-668-79276-6

Foreword

This is the 37th edition of the HEALTH LAW HANDBOOK, all edited by me. This book brings together 25 authors writing 14 stand alone articles addressing topics which fall under the 4 following rubrics: (1) The Changing Health Care System; (2) Transactional Issues; (3) Reimbursement and Payment; and 4) Fraud and Abuse.

There are many ways in which the health care system is changing, but the arrival of digital health and artificial intelligence (AI) cannot be overstated as an issue all health lawyers will have to confront. This is the topic tackled by Vanessa Burrows and Carolyn Metnick. They distinguish the two concepts and then survey the range of regulators who have a role in this context. That range is broad, including dueling Executive Orders on point, from one Presidential administration to the next, and the FDA's concepts of what constitutes a medical device, which includes software. European Union laws have extraterritorial impact to consider as contrasted with the incipient dynamism in state laws seeking to protect consumers from a variety of applications, particularly of AI, as used in prior authorizations and determinations of medical necessity, for example. They present examples of risks under traditional principles of law and conclude with a discussion of enforcement efforts so far. This is a brisk review of what is fast becoming a mandated topic for all health lawyers to be familiar with.

Another wide ranging phenomenon is the advent of private equity (PE) in healthcare. Whether you are pro, con or agnostic regarding this development, understanding from whence it has sprung and what drives it is important to appreciate why their deals are structured as they are. Rather than presenting the documents that make for a private equity transaction, Matt Miller and Kim Harvey Looney offer a broader consideration of the context and motivations of private equity. They address how PE emerged as an investment vehicle and how PE differs from other types of investments. They have analyzed four essential factors which

influence PE behaviors and a framework (with a schematic) to understand its goals and mechanisms. The law is one of those factors. They present the current major criticisms of PE and take into account some state legislative developments and federal enforcement efforts. This is a different and illuminating approach to a high profile development in healthcare.

The massive consolidation in the health care industry has been noted by many commentators for a good number of years now. This makes Wendy Arends' piece on top trends in merger enforcement a must read to understand what regulators are doing. Major changes in the guidelines applicable to mergers focus on market power and market consolidation. She presents those guidelines along with what has happened in the overhaul of Hart-Scott-Rodino rules. She offers caselaw addressing government efforts and also addresses the enforcers' lens on private equity in health care as it relates to antitrust. She moves onto labor markets and issues that arise there including in non-healthcare sectors. She touches on the ban on non-competes and concludes with a consideration of developing state law developments. This is a plain English presentation of complex issues in truly dynamic times.

Turning to the second topic of transactional issues, all healthcare transactional lawyers read and write representations in their deal documents. Ari Markenson and Chris Conn offer a consideration of typical representations and warranties in healthcare transactions. They elucidate the topics usually covered and address qualifiers that can apply to them. They offer model language for 13 separate representations and warranties and 9 definitions of critical terms. This is a down to earth approach to terms any transactional lawyer will encounter, specifically in the healthcare context.

In a thorough explication of issues in alternative dispute resolution (ADR), Chris Sabis and Gary Qualls present a sweep of information from the rules that govern ADR, to 8 benefits of using ADR while contrasting that with the benefits of court litigation. They provide a framework to set boundaries in agreements for ADR (invoking Star Trek along the way) and give bountiful reasons as to why brief ADR provisions are not necessarily the right answer. They ad-

dress 11 sets of considerations to take into account, the options among them and then recommendations, often providing proposed language. They also offer some insight into the differences among ADR service providers. This is an informative article from experts with real world experience in their topic.

Focusing on the use of non-competes in physician employment, Jantzen Mace and Samuel Lillard provide an interesting survey of the history of these contractual clauses going back to 1414 (that is not a typo)! They then move to the application of these restrictions in health care, examining closely the AMA's evolving position. They present arguments pro and con non-competes in health care employment specifically, and then move on to federal attempts to regulate them. Both the FTC and the NLRB have engaged in recent activity in this regard; and the courts have confronted this dynamism as well. The authors offer information about state level restrictions on non-competes, and generally opine that the overall movement is toward limits on them, but the issues will remain in flux for some time.

The third section of the book regarding reimbursement and payment opens with Christina Hughes' take on the longstanding and shifting policy regarding provider-based reimbursement in Medicare. Provider-based status permits a hospital to be paid more under Medicare for its outpatient services than other comparable outpatient settings. The fact of this differential is not only relevant to hospitals themselves, but also to those who would do business with them. The potential partners ought to understand why a hospital would seek provider-based status and what is required to do so. Christina unravels the complexities here from rules regarding proximity, to integration and on and off campus distinctions, including waivers. She addresses issues regarding public awareness, special concerns with management contracts and under arrangements relationships as well as enrollment. She describes 6 advantages to taking on this status, but also 4 disadvantages. In that context she describes the developments regarding site neutral policies which seek to tamp the effect of provider-based status. She also observes a significant list of physician dissatisfactions with provider-based status. This is a handy guide to some complex issues in the hospital payment space which can

impact others as well.

In the world of payment, managed care organizations (MCOs) have come to dominate the Medicaid landscape, by a lot. Where providers are dissatisfied with the determinations of these private entities paid for with state and federal funds, they turn to challenges based on constitutional issues under Section 1983. The dichotomy of private entities taking on significant functions of the state programs raises the issue of whether the MCOs qualify as "state actors" subject to the federal challenges often launched against them. Andrea Kerstein, Heidi Brady and Alyssa Gregory examine the 4 different tests which can be dispositive of these decisions. They reach back to the 1990s and review significant caselaw on point up to the present. While the law generally favors the MCOs and not the complainants, whether regarding operation of these programs, payment amounts, benefits or other actions, the law also does not preclude any such challenges. This is a crisp review of a lurking impediment to Medicaid program challenges.

Next, in an in-depth consideration, Susan Banks confronts the challenges associated with overpayments, primarily in the Medicare fee for service program. Generously footnoted, her article discusses the obligation to report and return monies, including lookback periods, along with the dynamism in the new rules regarding identifying overpayment amounts; "quantification" is no longer the issue. It is now investigations and the different time periods to conduct them. She then moves on to distinguish what is and is not an overpayment, since not all compliance errors actually meet the standards. She assesses the implications of 5 landmark Supreme Court cases and then moves on to other federal healthcare program overpayments, including to beneficiaries. She concludes with practical guidance for providers. Understanding the issues she presents, has become fundamental for health lawyers who work on payment and compliance issues.

A principal government mechanism to determine whether overpayments have occurred is through audits. In their article, Lindsey Lonergan, Ross Burris and Evan Schrode examine this technique for program integrity. They address who the auditors are and on what they base their

determinations. They explain the various types of audits and when they are likely to occur, including how they can escalate, They consider the overpayment and repayment rules in this context, but also include two self-disclosure processes and their application in this arena. They present techniques to defend against audits including appeals, to whom they ought be made and within what timeframes. They follow with 6 specific pro-active strategies to prevent audits and manage them within the provider setting, including detailed guidance regarding how to implement their suggestions. This is an excellent companion article to the overpayment piece. Reading them in tandem is really useful.

In the fourth section, fraud and abuse remains at the forefront of health care regulation. Taylor Chenery, John Eason and Travis Lloyd contribute their now, almost traditional, update on recent developments. They begin with the new OIG industry specific compliance guidance for nursing facilities. They move to a Fraud Alert on Medicare Advantage marketing. Noting 13 OIG Advisory Opinions in 2024, they highlight several of them, including two unfavorable opinions. They take the overpayment rule into account with some specific criticism of its new form. They look at the self-referral disclosure protocol for which there were an amazing 6 and a half times more submissions in 2023 than two years previously. Shifting to court decisions regarding anti-kickback and Stark, they review the circuit splits that characterize this topic. They present noteworthy settlements which are such in terms of breadth, scope and volume of them. Moving to the False Claims Act, the dynamism and volatility of issues here continue, beginning with an opinion declaring the qui tam provisions unconstitutional. Particularity was the flaw in multiple cases in different ways. Presentment of false claims was the issue in other cases. Post-*Escobar*, materiality continues to be addressed by the courts and the authors. Scienter was at issue in a variety of ways as was the public disclosure bar, damages, and retaliation against whistleblowers. They conclude with some information on criminal enforcements. Fraud and abuse is a major issue for all health lawyers. Their treatment of it always provides a solid foundation to understand developments that keep occurring at breakneck speed.

In 2016 I wrote about the then newly burgeoning phenomenon of Medicare paying physicians for services that involved no face to face time with the patient. Now almost ten years later, not only have these types of payable services expanded, the OIG has paid some attention with settlements and investigations when physicians get these services wrong. My article first addresses traditional forms of non-face time services such as incident to, split/shared visits and care plan oversight and then moves through the more modern services of transitional care management, chronic care management, remote physiologic monitoring and concluding with the 2025 new service of advanced primary care management. I explain the details of what each requires, describe any relevant OIG actions, and proffer where physicians are likely to fail in documenting and billing effectively. I then review the potential implications of the three significant Supreme Court cases of *Escobar*, *Allina* and *Loper Bright* (as do others in their articles). As the gradual shift to more value-based payments has mandated more coordination of care, these services represent a potential benefit to pay physicians for what they actually do; but they also present a real risk area for them.

Dan Shay tackles issues in Medicare enrollment beginning with a history of the progression of the actual enrollment forms and the approaches they represent. He addresses two styles of advice—one regarding general advice and the other in defense against false claims allegations. He considers multiple Supreme Court cases going beyond the triumvirate many of us discuss here. He confronts the regulatory hierarchy of regulations, forms and manuals in light of caselaw. He addresses the differences in analysis among cases under the Administrative Procedures Act, the Medicare Act and the Paperwork Reduction Act. His close reading of these cases as applicable in the specific context of defense is enlightening. He concludes with real life scenarios and practical challenges. This is a well thought out consideration of thorny Medicare issues.

Federal payers are not the only agents who assess claims for payment as part of their program integrity efforts. Clinical validation is a little understood process by which health

plans over-ride clinical judgments of physicians as submitted by hospitals in their claims for DRG payments. Richelle Marting lifts the shroud on this process with which most lawyers are unfamiliar. She explains ICD-10 coding and its role in determining DRGs. She distinguishes validation techniques between DRG validation and clinical validation. She further differentiates resulting adjustments to claims versus denials. She observes that there is not only a lack of uniformity in the way health plans conduct clinical validation, but the standards themselves are not uniform. She then considers some legal implications from all of this including who is making these determinations and whether there are state law requirements regarding licensure, operation of utilization management and utilization review programs, as well as determinations of medical necessity. Her article is a shining light on a dark but impactful phenomenon.

Several of the articles in the book address the same Supreme Court cases which have rattled healthcare in recent years. It is not often that health lawyers have to confront constitutional issues. Other groups of articles touch on issues which relate to each other, but from differing perspectives. To me, this is one of the great values of the contributions here. To read all the articles is a truly valuable undertaking. I have done it 37 times; and I am convinced it has made me a better lawyer. I encourage our readers to do the same. To the contributors, I offer my profound gratitude for their willingness to share their intellectual capital with colleagues, here. They are the essence of professionalism. I hope our readers appreciate the level of effort they have expended. I offer my thanks to those who have written as well as those who will read.

Alice G. Gosfield

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About the Editor

ALICE G. GOSFIELD, Esq.'s entire legal career has been restricted to health law with a focus on non-institutional reimbursement including from Medicare, as well as managed care, fraud and abuse compliance and avoidance, medical staff issues and utilization management and quality issues including clinical integration, with an emphasis on representation of physicians and their group configurations. A graduate of Barnard College and New York University School of Law, since 1973 her varied health law career has ranged from an OEO ("War on Poverty") and then DHEW funded research program to develop a consumer-oriented analysis of the PSRO law, to drafting codes of regulations for state health care agencies, and since 1978 to include the private practice of law.

Ms. Gosfield served as Chairman of the Board of Directors of the National Committee for Quality Assurance (www.ncqa.org), reelected to serve five terms from 1998 through 2002. She was a member of the Board from 1992 through 2002. In the public policy arena, she has served on four committees of the Institute of Medicine of the National Academy of Sciences studying issues involving utilization management and clinical practice guidelines and has served as an advisor to the Agency for Health Care Policy and Research in both evaluating one of their first three clinical practice guidelines and in developing methodologies to translate guidelines into medical review criteria, performance measures and standards of quality. She has been called on by the Congressional Budget Office, the General Accounting Office, the Robert Wood Johnson Foundation, the Federal Agency for Healthcare Research and Quality and others to advise on issues pertaining to Medicare reimbursement, medical evidence, legislation dealing with medical necessity in managed care and tort reform.

A highly sought after speaker, Ms. Gosfield has been invited to lecture throughout the country and internationally to diverse audiences including physicians and other health care professionals, chief executives and chief financial

officers, boards of trustees and directors, group managers, managed care executives and others throughout the health care industry. She is noted for her practical yet provocative, incisive, down-to-earth style and ability to make complex technical information understandable as well as entertaining. She has lectured often for a variety of organizations including the American Health Lawyers Association (AHLA), the American Medical Association (AMA), the Medical Group Management Association (MGMA), the American Association of Health Plans (AAHP), the Health Care Compliance Association, and the American College of Cardiology as well as other national, state and regional groups.

A frequent author in a wide range of health care publications, she has authored or co-authored more than 200 published articles, 11 monographs and three other books. Her first book "*PSROs: The Law and The Health Consumer*" was published in 1975. Her second book—*Guide to Key Legal Issues in Managed Care Quality*—was written primarily for non-lawyers and published in 1996 by Faulkner and Gray. Since 19890 she has been the editor of this HEALTH LAW HANDBOOK. She also co-authors with Daniel F. Shay MEDICARE AND MEDICAID FRAUD AND ABUSE, an annually updated treatise. She has served on the editorial boards of multiple diverse journals and newsletters including *Healthplan* (published by AAHP), *Medical Economics*, *Managed Care, Family Practice Management*, and *The Journal of Health Care Compliance*.

Ms. Gosfield served as President of the American Health Law Association (formerly the National Health Lawyers Association, (www.healthlawyers.org) from 1992-1993 and Chaired their Physician and Physician Organizations Institute for six years. She also chaired their last and final Masters Program. She has been a member of several physician-organization sponsored consulting networks including those of the AMA, the American College of Physicians, the American Academy of Family Physicians, and the American Society of Plastic and Reconstructive Surgeons.

She has been listed in *The Best Lawyers in America* (Health Law) in every edition since the inception of the health law category in 1991. She has been recognized internationally for her health law expertise by the International Centre for Commercial Law in the United Kingdom as

one of The Legal 500, a select group of 500 law firms in the United States recommended for their specific abilities in particular areas of the law. She is recognized as a band 1 national lawyer by Chambers which describes her as a "luminary" in the field. She was named one of the top 30 health lawyers in the country in 2007 by the Best of the Best and among the top 25 health lawyers nationally in 2009. She is listed in many other rankings of top lawyers nationally, including being named by CEO Time magazine as one of the most visionary women leaders of 2024.

About the Contributors

Wendy Arends is a partner with Husch Blackwell LLP, a member of its healthcare life sciences and education business unit, and a co-leader of the firm's antitrust group. She guides clients through pending merger reviews and challenges before U.S. DOJ, the FTC, and state attorneys general, and counsels clients regarding proposed transactions and collaborations, market allocation, pricing and distribution issues, and a wide array of antitrust compliance issues in healthcare and other industries. She represents clients in antitrust investigations and litigation. She is currently co-chair of the ABA Antitrust Section's Mergers & Acquisitions Committee and co-authored a variety of publications, including the *Antitrust Law Developments Update*, the *State Antitrust Enforcement Handbook*, and the *Antitrust Source*.

Susan Banks is a partner at Holland & Knight LLP who advises hospitals, health systems and other healthcare providers and suppliers on the full range of federal and state health care compliance requirements, with a particular focus on issues that impact Medicare and Medicaid payments. Susan has deep knowledge and experience with Medicare reimbursement mechanisms, including associated coverage policies and billing rules. She regularly counsels clients regarding compliance matters and assists them with internal investigations of potential federal health care program overpayments and, when needed, helps them make appropriate self-disclosures and voluntary refunds. She also has experience advising and representing clients in connection with suspected instances of fraud and abuse arising under the federal False Claims Act, Stark Law, Anti-Kickback Statute, and their state law analogues, and has represented healthcare clients in connection with investigations and audits undertaken by the gamut of federal and state regulatory and enforcement agencies. In the transactional arena, Susan helps clients develop the right deal structure and strategy to meet their business goals while assuring reimbursement compliance and managing potential regulatory risks.

Heidi Brady is a partner in Troutman Pepper Locke's Chicago office and has substantial experience representing clients in the insurance, reinsurance, and health care industries. Concentrating her practice on complex litigation, arbitration, and health care regulation, she handles matters involving breach of commercial or government contracts, business torts, trade secret and unfair competition claims, insurance insolvency litigation, state guaranty funds, and insurance fraud. Heidi assists clients throughout the entire litigation or arbitration process, including case evaluation, discovery, pleadings, motions, hearings, trials, post-trial, and appeals. She also represents clients before state insurance departments, including provider appeals, guaranty fund surcharge disputes, and major health care insurance acquisitions.

Ross Burris is a shareholder in the Atlanta office of Polsinelli and Co-Chair of the firm's Reimbursement Audits and Dispute group. Ross focuses his practice on representing providers facing payor audits, overpayment demands, and False Claims Act investigations. He provides tailor-made, practical solutions to reimbursement issues and audits by government payors, commercial plans, and investigative agencies, including actions against commercial payors in court and arbitration, as well as representing provider issues through the labyrinth of federal and state payor appeals and arbitration litigation. His compliance work encompasses advice on federal and state health law regulations, including Medicare Reimbursement Audits, Medicaid issues and Commercial Payor disputes and Medicare billing guidelines. Nationally known, Ross has been recognized multiple times in the area of health care law by Chambers USA, Super Lawyers, and Best Lawyers in America.

Vanessa K. Burrows is a partner in Simpson Thacher & Bartlett LLP's Washington, DC office. Vanessa has advised healthcare and technology companies, healthcare providers, and pharmaceutical and medical device manufacturers in connection with regulatory and compliance needs, mergers and acquisitions, and capital-raising transactions. Vanessa counsels clients with respect to FDA regulatory and enforcement matters, health privacy, security and breach is-

sues, and healthcare fraud and abuse matters. Previously, Vanessa held several government positions. She served as the HIPAA Privacy Officer and Attorney for the Department of Public Health for the City of Chicago. Vanessa also advised Members of Congress and their staff as a Legislative Attorney with the Congressional Research Service, including on laws that expanded FDA's regulatory and enforcement authorities. She handled healthcare law, administrative law and constitutional law matters during the creation and passage of the Patient Protection and Affordable Care Act (ACA). Vanessa has spoken at events including BIO International Convention, the Food and Drug Law Institute's Annual Conference, the American Health Law Association's Annual Meeting, and the International Bar Association's World Life Sciences Conference. She is also counsel of record for a U.S. Supreme Court amicus brief in an FDA case. Vanessa is a graduate of Valparaiso University, Queen's University Belfast, and American University Washington College of Law, where she serves on the Health Law and Policy Program Alumni Advisory Council.

Taylor Chenery, a partner at Bass, Berry & Sims PLC, centers his practice on government compliance and investigations and related litigation, focusing on issues of healthcare fraud and abuse. Taylor has significant experience representing a wide variety of healthcare clients in relation to government inquiries and investigations by the HHS-OIG, U.S. Attorneys' Offices, the DOJ, and other federal and state agencies. Taylor regularly litigates lawsuits filed under the FCA and conducts internal investigations and compliance assessments for healthcare companies and providers, advising them on compliance-related issues. He also routinely represents healthcare clients defending claims denials in Medicare and Medicaid claims audits.

Christopher E. Conn, JD, MPH, M. Ed is a corporate attorney at Venable LLP in its Baltimore, MD office. Chris focuses his practice on corporate, mergers and acquisitions (M&A), and regulatory matters related to the financial services and healthcare industries. Chris has represented both private and public clients in complex buy-side and sell-side transactions. He has experience representing health industry clients on matters relating to professional practice acquisi-

tions and structuring of professional practice and professional practice management businesses. He also regularly advises companies on various corporate governance matters. In December 2020, Chris was selected as Venable's Treanor Fellow and served a six-month fellowship at Maryland Legal Aid, where he represented tenants facing eviction in Baltimore City's rent court.

John Eason is a partner at Bass, Berry & Sims PLC in Nashville, TN. He focuses his practice on representing clients in government enforcement actions, investigations, and related litigation, particularly concerning healthcare fraud and compliance issues. John represents healthcare providers across the industry in responding to inquiries and investigations by the Department of Justice, U.S. Attorneys' Offices, HHS-OIG, and other government agencies. He has significant experience litigating actions involving federal False Claims Act, state equivalents, and other fraud statutes, as well as whistleblower anti-retaliation statutes. John also assists providers with internal compliance assessments and internal investigations regarding regulatory and compliance issues. John is a graduate of Georgetown University and Vanderbilt University Law School. After law school, he clerked for Judge Anita B. Brody on the U.S. District Court for the Eastern District of Pennsylvania.

Alyssa Gregory is a partner in Troutman Pepper Locke's Chicago office and focuses her practice on complex commercial litigation and arbitration matters. She represents insurers and reinsurers in insurance and health care disputes and arbitrations. She also has experience representing a broad array of clients involved in general commercial litigation matters, class actions, and trade secret misappropriation disputes. Alyssa's clients include reinsurers, health insurers, manufacturing, and construction companies, as well as consumer product companies. She tries cases, obtains summary judgments, represents clients in high-stakes arbitrations, and navigates complex litigation and regulatory issues. Alyssa also regularly advises life insurance companies regarding contestability and rescission of life insurance policies. She has been recognized as a *Super Lawyers* Illinois Rising Star for Business Litigation in 2023-2024.

Christina Hughes is a healthcare attorney practicing in Washington, DC at the firm of Powers Pyles Sutter & Verville, PC, a boutique firm specializing in healthcare, higher education, tribal, and nonprofit law. Christina focuses her practice on healthcare compliance, particularly as related to fraud and abuse matters and Medicare coverage requirements. She is also experienced with Medicare administrative appeals, primarily in the areas of inpatient rehabilitation, orthotics and prosthetics (O&P), hospice, and Two Midnight Rule-related denials. Specifically, Christina representation of hospitals and hospital systems, home health providers, physicians, O&P suppliers, pharmacies, and diagnostic and other health services providers includes: providing advice on compliance with the Stark law, the anti-kickback statute, and the federal False Claims Act, including self-disclosures to CMS and the OIG and voluntary refunds; analyzing and creating Stark law compliant contracts; providing counsel and legal assistance with Medicare claim denials and appeals, as well as other issues related to reimbursement; and counseling on compliance with Medicare coverage requirements for both hospital services and durable medical equipment and O&P supplies.

Andrea Verney Kerstein is the managing partner of Troutman Pepper Locke's Chicago office. She has significant experience representing insurers and reinsurers in complex insurance and health care disputes and arbitrations, primarily in the life and health insurance areas. She has deep experience representing plaintiffs and defendants in commercial litigation and arbitration matters. Andrea's clients range from national health insurance companies to life reinsurance firms, frequently representing them in disputes involving breach of contract, fraud, and reinsurance treaty issues. She represents her clients as the plaintiff in complex matters, obtaining pre-trial settlements ranging from the multimillions to billions. Andrea is recognized by *Best Lawyers in America* for Health Care Law and was named a Notable Women in Law by *Crain's Chicago Business* in 2024.

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Lindsey Lonergan currently serves as a Senior Associate General Counsel of Wellspan Health which is a large health system headquartered in Pennsylvania. Prior to that LIndsey was Vice President and Deputy General Counsel at Atrium Health Navicent in Macon, Georgia. Lindsey provides legal advice and services to the health system on healthcare operational matters, regulatory and compliance matters, company transactions, and ongoing litigation. Lindsey was

also responsible for development and oversight of system contracts for multiple business units and divisions as well as clinical service lines across the enterprise and oversaw strategic enterprise risk identification, prevention and management including legal management of internal compliance investigations. Lindsey obtained her Juris Doctorate from the University of Georgia School of Law in Athens, Georgia. In addition, she received her Master of Health Science (MHS) in Health Policy from Johns Hopkins University in Baltimore, Maryland. Lindsey is also Certified in Healthcare Compliance by the Compliance Certification Board (CCB) and a Certified Information Privacy Professional (CIPP/US) with the International Association of Privacy Professionals (IAPP).

Kim Harvey Looney is a partner in the Nashville office of K&L Gates LLC and a member of the firm's Healthcare and FDA practice group. Kim regularly works with healthcare clients, including for-profit and nonprofit healthcare providers, academic medical centers, physician practices, post-acute providers, ambulatory surgery centers, and integrated delivery systems, on operational issues such as licensing, state matters, Medicare certification and reimbursement, reimbursement audits, contracts, corporate governance, CON applications and hearings, and recruitment and employment. She also has significant experience advising and assisting clients with regulatory issues related to structuring mergers, acquisitions, and joint ventures. She regularly advises clients on compliance issues related to federal and state laws (such as Stark, Anti-Kickback, Civil Monetary Penalties Law, False Claims Act, fee splitting laws, corporate practice of medicine, etc.). Other areas of expertise include government investigations, provider enrollment and credentialing, and CMS/OIG self-disclosures. Kim is a frequent author and speaker on healthcare legal issues for the American Health Law Association and the Tennessee Bar Association, among others. She has been named to the *Nashville Post's* In Charge list as a leading health care attorney and by the *Nashville Business Journal* as a "Woman of Influence," "Healthcare Hero" and "Best of the Bar." Kim has frequently been named to the list of *Mid-South Super Lawyers*, *The Best Lawyers in America* and has been recognized by Chambers for her work in the healthcare

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Jantzen D. Mace is an attorney at Ogletree, Deakins, Nash, Smoak & Stewart, P.C. His practice is focused on all aspects of labor and employment law. He represents a broad range of employers, including those in the manufacturing, transportation, food, retail, and healthcare industries. Though Jantzen's practice is primarily focused on employment litigation defense, he also counsels employers on key employment issues such as leave laws, discrimination and harassment concerns, accommodation requests, and employee non-compete obligations. Jantzen holds degrees from Miami University and The Ohio State University Moritz College of Law, where he earned a Certificate in Alternative Dispute Resolution in addition to his Juris Doctor.

Ari J. Markenson, JD, MPH is a healthcare and corporate partner at Venable LLP in its New York City office. He practices at the intersection of healthcare, law, and business. Ari advises healthcare industry clients, including investors, lenders, providers, and suppliers, on a broad range of regulatory and corporate matters, and has significant experience in complex healthcare industry acquisitions and financial transactions. He regularly represents investment firms and lenders in such transactions and evaluates and advises on compliance and regulatory issues with regard to sellers and potential borrowers. He also advises various healthcare entities on regulatory matters, including conditions for participation; fraud and abuse; and survey, certification, licensure, and enforcement issues. He is a former Chair of the New York State Bar Association, Health Law Section, and a current member of the Board of the American Health Law Association. Ari frequently writes for industry publications and speaks at industry and professional events. He is the author, co-author or editor of six books on health law topics and two book chapters. Over his career, Ari has written over 65 articles on health law issues and spoken more than 80 times at industry and professional events. He also teaches healthcare law, public health law, healthcare lawyering skills, and other healthcare management and policy topics at the Columbia University Mailman School of Public Health, Columbia Law School, the Pace University College of Health Professions—Department of Health Science, and the Elisabeth Haub School of Law at Pace

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Richelle D. Marting is a healthcare attorney and certified professional medical coder who founded Marting Law, LLC after nearly ten years of private practice in a boutique healthcare law firm. Marting Law, LLC now employs a team of attorneys who are also registered health information administrators and certified medical coders, as well as non-attorney healthcare professionals. Richelle's practice focuses on reimbursement matters for healthcare facilities and professionals. She has served in-house roles ranging from director of managed care contracting, interim health system privacy officer, and compliance coordinator, to medical coder and certified nurse aide. She and her team review thousands of medical claims each year and have successfully recovered or retained tens of millions of dollars for the healthcare organizations they represent. Richelle has a special interest in physician practice and hospital inpatient reimbursement issues, and the intersection between healthcare payment, medicine, and the law. She has also served as an expert in litigation supporting attorneys on matters related to health information management, reimbursement, and privacy.

Carolyn Metnick is a partner in Sheppard Mullin's Chicago office. Carolyn represents a range of healthcare industry clients, including hospitals and health systems, physician organizations and digital health companies. She advises on healthcare regulatory and transactional matters with a focus on health information privacy and security. Carolyn is the founder and leader of Sheppard Mullin Healthy AI, which is an initiative focused on legal issues relating to the use of AI in healthcare. She counsels healthcare clients on issues relating to AI, including governance, contractual matters, and data related issues. Carolyn advises clients on a range of privacy and security laws, including HIPAA and other federal and state privacy laws. She also counsels businesses in data breach investigations and compliance with federal and state breach notification laws. Carolyn is a Certified Information Privacy Professional/ United States (CIPP/ US) and a Certified Information Privacy Professional/Europe (CIPP/E).

Matthew Miller is a partner in the Nashville office of K&L Gates LLP and a member of the firm's Healthcare and

M&A practice groups. Matt focuses on mergers and acquisitions, private equity, and venture capital transactions, both domestically and internationally. Within the healthcare industry, Matt has significant experience with Management Services Organizations (MSOs), Ambulatory Surgery Centers (ASCs), and healthcare technology companies. Matt also serves as outside general counsel to public and private companies regarding a broad range of business and contractual matters, including equity financing and joint ventures. Matt is a frequent author and commentator on issues affecting the business and legal community. His commentary has appeared in publications such as *Bloomberg Law*, *Law360*, the *Nashville Business Journal*, and many others. Matt was named as one of *Bloomberg Law*'s top "40 Under 40," recognizing the nation's most accomplished legal minds. He has also been consistently recognized in *The Best Lawyers in America*.

Gary Qualls is a partner in K&L Gates' Healthcare Practice Group. He focuses his practice on representing healthcare clients and is a certified arbitrator with the American Health Law Association and the American Arbitration Association. Mr. Qualls is the former Chair of the AHLA's Dispute Resolution Service Council. He litigates, arbitrates, and mediates healthcare disputes, including disputes involving the following issues: payment and reimbursement; certificate of need; licensing and certification; HIPAA; contracts of all types; medical staff privileges; EMTALA; and civil monetary penalties.

Christopher C. Sabis is a Member at Sherrard Roe Voigt & Harbison, PLC, in Nashville, Tennessee, where he concentrates his practice in Government Investigations, Litigation, and Alternative Dispute Resolution. Much of his work involves fraud and abuse matters, with particularly extensive experience defending and mediating False Claims Act cases involving allegations of healthcare and procurement fraud. He also has significant experience serving as an arbitrator in healthcare and other commercial disputes. Chris is on the American Arbitration Association's Roster of Arbitrators' Commercial and Healthcare Arbitration Panels and serves on the American Health Law Association's Dispute Resolution Service Council. He has been a federal court-appointed

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Daniel F. Shay is an attorney with Alice G. Gosfield and Associates, P.C. His practice is restricted to health law and health care regulation focusing primarily on physician representation, fraud and abuse compliance, Medicare Part B reimbursement, and HIPAA compliance in the physician context. He also has a keen interest in intellectual property issues, including copyright, trademark, data control, and confidentiality. He has also focused his attention on provider control of commerce in data, electronic health records license agreements, physician advertising, enrollment in Medicare, quality reporting and quality measurement, physician use of non-physician practitioners, and physician use of social media. He has published on all these topics both in the trade press and in major articles in previous years of the HEALTH LAW HANDBOOK. Mr. Shay received his Bachelor of Sci-

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