About the Editors

Emily Black Grey is a Partner with Breazeale, Sachse & Wilson, L.L.P. She is a board-certified Health Law Specialist who has practiced health law for almost 25 years. She is a member of the firm's Management Committee, and Best Lawyers has named her the 2024 "Lawyer of the Year" in Health Care Law in Baton Rouge. Emily is one of only three Louisiana lawyers ranked in Band 1 by *Chambers USA*.

Emily's clients describe her as "extremely knowledgeable and extraordinarily helpful." She is known for her experience in the field, particularly in the intersection of state regulatory and federal requirements. Her clients include hospitals, behavioral health providers and addiction treatment centers, surgery centers, pharmacies, physicians, laboratories, healthcare management and consulting companies and other healthcare businesses. She represents healthcare providers in operational matters, regulatory and compliance issues, contracting, licensing and enrollment, reimbursement and payment disputes, healthcare transactions, and other business matters. Healthcare providers have also engaged her as a health law expert in litigation and arbitration.

Emily currently serves on the American Health Law Association Board of Directors. She has also held leadership positions in the American Bar Association House of Delegates (which establishes national ABA policies), the Louisiana State Bar Association's Health Law Section (as Vice Chair), the Louisiana Law Institute (the state's official law revision commission), and the Baton Rouge Bar Association. She is also a frequent speaker and author on health care issues, with more than 130 presentations and publications, including many for the American Health Law Association and the Louisiana Hospital Association. Emily is licensed in Louisiana and Texas, is a health law arbitrator, and has served as adjunct faculty, teaching health law at the LSU Law Center.

Travis G. Lloyd is a partner at Bass, Berry & Sims PLC in Nashville, Tennessee. He focuses his practice on complex health care regulatory matters, particularly in the areas of fraud and abuse, reimbursement, and the licensure, certification, and accreditation of health care facilities. Travis represents a broad range of health care industry clients, with a particular focus on hospitals and health systems. His experience includes acting as regulatory counsel on significant transactions, guiding health care providers through thorny compliance issues, obtaining advisory opinions, managing internal compliance reviews and investigations, representing health care providers in administrative appeals, and making voluntary disclosures to government entities. Travis is an active member of the AHLA and previously served on the editorial board of its *Journal of Health & Life Sciences Law*. Travis is a graduate of Davidson College, Georgia State University, and Harvard University.

Susan O. Scheutzow is Of Counsel with Kohrman Jackson & Krantz LLP and serves as General Counsel for Southwest General Hospital. She works with clients on regulatory and compliance matters, medical staff and licensing issues, contract negotiations, litigation and general corporate law. Susan's contributions to the field of health care law across her 40-year legal career have been recognized locally and nationally. She is a current fellow and former board member of the American Health Law Association, was honored with the Distinguished Women in Healthcare award from the Visiting Nurse Association, and is often called upon to speak on healthcare law topics and contribute to such publications as the *Journal of Health & Life Sciences Law*. She is an attorney equally respected among medical staffs and healthcare executives. Susan has pioneered the curriculum in Health Law at Cleveland State University's Cleveland-Marshall College of Law and continues to teach graduate and undergraduate courses in health law at Baldwin-Wallace University.

Claire M. Turcotte is currently Director of Legal Services Special Counsel at Premier Health, where she is counsel for strategy and business development including health system partnerships and joint ventures as well as regulatory counsel for reimbursement and health information. Prior to joining Premier Health in 2020, Claire was a partner at Bricker & Eckler in Ohio where she focused her practice on health care transactions, hospital-physician contracting, physician compensation, fraud and abuse, provider-based status and other Medicare and regulatory matters.

Claire has been an AHLA member since 1993 and has served in several leadership roles including as a member of the OIG Advisory Opinions Task Force for the Fraud and Abuse Practice Group, Vice Chair of the Hospitals and Health Systems Practice Group, member of the inaugural Women's Leadership Counsel, and member of the Quality Councill. Claire has also contributed to AHLA as an author and speaker at in-person programs, webinars, and podcasts.

About the Authors

Stephen M. Angelette, co-author of Chapters 1 through 4, a shareholder with Polsinelli, is board certified in health law by the Texas Board of Legal Specialization. He has extensive experience with structuring health care arrangements in compliance with the Anti-Kickback Statute and Stark Law, as well as other state and federal health care laws, and has advised on the health care regulatory aspects of hundreds of equity and asset purchases of hospitals, home health agencies, hospices, pharmacies, laboratories, physician groups, and urgent care centers. In addition to transaction structure and evaluation, he provides guidance to health care providers and suppliers related to their enrollment and operational compliance with Medicare, Medicaid, and various state licensing agencies and assists in responding to government inquiries, suspensions, or terminations of such facility enrollment or licensure.

Alexis L. Angell, author of Chapter 22, is a Health Care Litigation Shareholder at Polsinelli, a national law firm with a strong health care practice. Alexis focuses her practice on medical staff, credentialing, and peer review matters. She advises and represents health care entities on complex legal issues, such as quality of care, competence, conduct, behavior, and wellness of health care professionals as well as reports to the National Practitioner Data Bank and state licensing boards. Her mission is to help clients navigate the challenges and risks associated with medical staff governance and performance improvement. She works closely with hospital counsel, Medical Staff leaders, Chief Medical Officers, Chief Executive Officers, and Medical Staff Directors to manage issues early and prevent unnecessary litigation. Alexis served as the 2023–2024 Chair of the American Health Law Association's Medical Staff, Credentialing, & Peer Review Practice Group.

Evelyn S. "Evie" Atwater, co-author of Chapter 14, focuses her practice on regulatory and transactional matters affecting hospitals, health systems, and other health industry clients. Evie advises clients on a variety of issues, including licensure, accreditation, fraud and abuse matters, and compliance programs. She also conducts due diligence on health care transactions.

Thomas Barker, co-author of Chapter 11, a partner with Foley Hoag, focuses on complex federal and state health care legal and regulatory matters with a special expertise in Medicare and Medicaid law, including coverage, reimbursement and regulatory oversight. He represents healthcare providers and payers before the Centers for Medicare & Medicaid Services (CMS) and other components of the Department of Health and Human Services (HHS) and the United States Congress.

Marie Berliner, co-author of Chapter 21, has been a health care regulatory attorney since 1988, representing health care providers on Medicare, Medicaid, and state law issues related to licensure, certification, compliance, and enforcement actions including surveys and licensure/termination actions, corrective action plans, and administrative penalty cases; as well as the Emergency Medical Treatment and Labor Act (EMTALA) Law. Before joining Joy & Young, LLP as Senior Counsel in 2012, Ms. Berliner was a partner in the firm Lambeth & Berliner, PLLC, where she focused on regulatory and transactional issues for home health agencies and hospice providers. Prior to that, she worked in the Washington, D.C. offices of Gardner, Carton & Douglas, and Wood, Lucksinger & Epstein. She has been a member of the American Health Law Association since 1988. Ms. Berliner graduated from the George Washington University School of Law after obtaining her undergraduate degree at Tufts University. She is a member of the Texas Bar, and an inactive member of the Maryland Bar and District of Columbia Bar.

Deborah Biggs, co-author of Chapter 25, is Principal and Director of Academic Medicine Consulting Services at PYA, P.C. Deborah has worked in academic medicine for more than two decades, having served as the chief operating officer at the University of Wisconsin School of Medicine and Public Health (UW) and Central Michigan University College of Medicine (CMU). Her previous experience includes working as a founding team member of a new medical school at CMU and working at three research-intensive universities (UW, University of Michigan Medical School, and University of North Carolina School of Medicine). She has extensive experience in governance models, healthcare regulatory compliance, mergers and acquisitions, strategic and financial planning, organizational and program development, policy and procedure development and implementation, and health care operations improvement. Prior to joining PYA, Deborah most recently served as entrepreneur and general counsel for three health care technology start-ups.

Ryan P. Blaney, co-author of Chapter 23, a partner with Jones Day, advises clients on regulatory investigations, enforcement actions, litigations, cyber incidents, compliance, and corporate transactions in the areas of data privacy, cybersecurity, health care, and artificial intelligence (AI). He has two decades of experience representing health care entities, life sciences, private equity, financial services, retail companies, and technology firms.

About the Authors

Kelly A. Carroll, co-author of Chapter 6, is a Partner in Hooper, Lundy & Bookman's Regulatory Department and Co-Chair of the firm's Medicare Appeals Practice Workgroup. Her practice focuses on Medicare and Medicaid reimbursement, and she regularly represents clients in disputes before the Provider Reimbursement Review Board (PRRB) and in federal and state courts. Kelly assists health care providers with a broad range of regulatory compliance, reimbursement, and administrative law matters. In addition, she advises health care providers and state Medicaid agencies on matters involving federal funding of state health care programs and disputes with the Centers for Medicare & Medicaid Services (CMS). Kelly also provides guidance on legal and ethical issues relating to informed consent and human subjects research and holds a Master of Bioethics degree.

Dominic Castillo, co-author of Chapter 31, is an associate with Husch Blackwell LLP. He helps providers navigate a highly regulated landscape so they can focus on optimal patient care. As part of the firm's Healthcare Regulatory & Compliance Counseling team, Dominic guides a wide range of clients—from individual practitioners to large national hospital systems—on ever-changing state and federal regulations. Skilled nursing facilities, assisted living facilities, hospices and home health agencies are among those relying on Dominic's guidance regarding compliance, transactional, and licensure matters including the Health Insurance Portability and Accountability Act (HIPAA); Medicare and Medicaid reimbursement; Stark Law compliance; the Anti-Kickback Statute (AKS); and the False Claims Act (FCA).

Richard Y. Cheng, author of Chapter 26, is an attorney and managing member of Ritter Spencer Cheng, PLLC. His legal practice focuses on health care and cannabis corporate transactions and regulatory matters. Richard represents a variety of health care and cannabis related clients (e.g. investors, industry providers, etc.) and was formerly an equity partner at a global Am Law 100 law firm where he chaired of the hemp/hemp cannabinoid products practice and a member of the health care sector. Richard has multiple distinctions—Thompson Reuters Superlawyer, D Magazine Best Lawyers, Top 200 Cannabis Lawyer by *Cannabis Law Journal* and a Top 250 Cannabis Legal Expert by *Databird Research Journal*. Lastly, Richard taught cannabis law as an adjunct faculty at UNT School of Law, issued multiple health care and cannabis publications and is certified in health care compliance (CHC) by the Compliance Certification Board (CCB).

Allison M. Cohen, co-author of Chapter 28, is a Shareholder with Baker, Donelson, Bearman, Caldwell & Berkowitz, PC. Her practice focuses on advising academic medical centers, teaching hospitals, health systems, and other for-profit and non-profit providers on a wide range of Medicare and Medicaid payment, coverage, and compliance issues. On behalf of clients, Allison also provides advice on structuring agreements and arrangements between providers and suppliers to comply with applicable billing and reimbursement requirements as well as federal fraud and abuse laws and regulations. She has experience with Medicare audits and appeals and representing health care organizations in Provider Reimbursement Review Board appeals.

Allison is active in providing regulatory counsel with respect to telehealth arrangements and agreements to provide other remote or digital health services. In this area, her practice includes analyzing and structuring telemedicine agreements between hospital systems, practitioners, and other health care providers. She regularly evaluates telemedicine arrangements and provides guidance regarding reimbursement, fraud and abuse, licensure, scope of practice, supervision, and corporate practice of medicine matters.

Sven C. Collins, co-author of Chapter 6, has spent most of his 25-plus-year legal career challenging the government's Medicare and Medicaid reimbursement and payment policies when they result in underpayment to his clients. His years of immersion in the laws and regulations governing reimbursement matters and his involvement in hundreds of payment disputes has afforded him insights on managing client issues efficiently to successful outcomes. Before agencies such as the Provider Reimbursement Review Board, in arbitration, in federal court, and at the appellate level, Sven advances his clients' interests to secure the reimbursements and payments to which they are entitled.

Hannah Comeau, co-author of Chapter 8, is an associate with Powers, Pyles, Sutter and Verville, P.C. She earned her J.D. from the University of Virginia School of Law in 2022. While attending law school, she interned for the Federal Labor Relations Authority, Office of the Solicitor, where she contributed to high impact district and appellate level litigation. She also worked as a student attorney in UVA's Appellate Litigation Clinic where she had the opportunity to argue a case in front of the United State Court of Appeals for the Fourth Circuit.

Hannah also served as Editor-in-Chief of the Virginia Journal of Social Policy & the Law during the 2021–2022 academic year. Additionally, she was a member of Lambda Law Alliance, Health Law Association, and served as Vice President of Student Outreach for the William Minor Lile Moot Court Board. During her time in law school, Hannah received recognition for completing UVA's Pro Bono Challenge through volunteering at organizations such as the Environmental Law Institute, the City of Idaho Falls Legal Department, and the Charlottesville Legal Aid Justice Center. Before law school, Hannah worked as a Medical Assistant at Madison Women's Clinic. In 2018, she graduated from Brigham Young University-Idaho with a Bachelor of Science in Sociology. While attending university, she was a part of

a specialized student research team, a Tutor, and a Teaching Assistant for upper-level sociology courses. Hannah was also the President of the Pre-Law and Sociology Societies.

Emily Cook, co-author of Chapter 7, is a Partner at McDermott Will & Emery, where she co-leads the Healthcare Regulatory & Compliance practice. Emily helps clients navigate the full suite of federal and state regulations that are essential to health care operations, including evolving issues such as Medicare drug price negotiation, development of new provider types, Medicare provider-based and co-location rules, and trends in qui tam litigation and government investigations. Emily is also a national authority on the 340B drug pricing program. Prior to joining McDermott Emily worked at the US Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA).

Amanda Coulter, co-author of Chapter 25, is an attorney with Coppersmith Brockelman. She regularly advises clients in the health care industry on clinical research matters. Amanda has extensive experience developing research compliance policies and processes, drafting and editing informed consent documents and HIPAA authorizations, and creating research-related policies and template agreements. Amanda assists clients by drafting, reviewing, and negotiating industry-sponsored clinical trial agreements, confidentiality agreements, data use agreements, material transfer agreements, investigator-initiated research agreements, research collaboration agreements, biological tissue supply agreements, professional physician services agreements, hospital services agreements, visiting scholar agreements, institutional review board reliance agreements, business associate agreements, and federal grants and subcontracts.

Bradley Cunningham, co-author of Chapter 28, is a Lead Policy and Regulatory Analyst at the Association of American Medical Colleges (AAMC), working within the Health Care Affairs cluster. Bradley completed law school in Washington, DC, and since joining the AAMC, has focused on policy issues related to graduate medical education.

Audrey Davis, co-author of Chapter 24, is an associate in Epstein Becker Green's Health Care and Life Sciences group, focusing her practice on telehealth and privacy, cybersecurity, and data asset management. Audrey counsels clients on compliance with U.S. state and federal laws affecting the provision of telehealth and telemedicine services, including issues related to corporate structure, scope of practice, licensure, online prescribing, reimbursement, and coverage. Audrey also assists clients with legal issues related to big data analytics and digital health strategies.

Jeffrey I. Davis, co-author of Chapter 8, advises health care organizations on Medicare and Medicaid billing and reimbursement issues, with a special focus on the federal 340B drug pricing program. He also counsels clients on emerging health care regulatory issues, including COVID-19 relief funding, surprise medical billing, and hospital price transparency, and provides strategic insights to clients on public policy matters under consideration by the U.S. Congress and federal agencies, such as drug pricing policy and nonprofit hospital issues.

Jeff forged his deep knowledge of the 340B program and other Medicare and Medicaid reimbursement issues while working in the federal public policy arena. He spent more than seven years working as vice president and legislative and policy counsel for 340B Health, an association of more than 1,400 hospitals and health systems participating in the 340B program. In this role, he provided technical assistance to member hospitals, directed research and policy efforts, and helped lead government relations efforts to educate federal policy makers on 340B issues. He draws on this experience to advise hospitals, pharmacies, other provider organizations and vendors on 340B issues including enrollment, contracting, audits, compliance and self-disclosures.

Lisl J. Dunlop, co-author of Chapter 33, has more than 30 years of experience providing antitrust support for her clients' key strategic initiatives, including major transactions and agency investigations. She guides clients through the antitrust-related aspects of mergers and acquisitions, joint ventures and other combinations, and agency investigations.

Lauded as a leading antitrust practitioner, Lisl provides a global perspective to approaching antitrust aspects of transactions, litigation strategy, and government investigations. Having practiced in Australia, the UK, and the United States, she is adept at representing clients before the U.S. federal and state antitrust enforcement agencies, as well as international authorities.

Lisl represents clients in a broad range of industries—including the technology, media, and cannabis sectors—and has mounted a significant health care practice. She guides healthcare companies in addressing antitrust risk in transactions as well as a variety of other initiatives, such as accountable care organizations, independent physician networks, and financial and clinical integration issues. Lisl is a sought-after author and speaker on antitrust and competition law.

Andrea Ferrari, co-author of Chapters 27 and 29, is Principal and General Counsel of a national health care solutions provider, where she serves clients inside and outside the company. Previously, she was a partner in the corporate practice group and health care industry team for a large national law firm, and partner at a national health care valuation and consulting firm, where she led service lines focused on value based care, clinical research, and provider recruitment and retention. She has provided counsel, representation, and advisory services for various types of clients, including hospitals and health systems, physicians and physician groups, pharmaceutical and medical device vendors, distributors, and

manufacturers. Andrea previously served as associate general counsel of a public health system that delivered rural and regional trauma care and has served as Chair of AHLA's Public Health Systems Affinity Group, which was dedicated to the unique legal issues for the nation's more than 1,100 public and safety net hospitals and health systems.

Jon Ferry, co-author of Chapter 17, is a partner with Bradley Arant Boult Cummings LLP. He assists clients in internal and government investigations, False Claims Act litigation, and other civil and criminal enforcement actions. He has significant experience in health care fraud and abuses statutes and regulations including the False Claims Act, the Anti-Kickback Statute, and the Stark Law. Jon's clients include health systems, diagnostic testing laboratories, skilled nursing facilities, hospice providers and home health providers, and physicians practices.

Jon served as Assistant U.S. Attorney for the Western District of North Carolina for more than seven years. As the head of the Affirmative Civil Enforcement (ACE) program, Jon developed and led the Healthcare Fraud False Claims Act program in the Western District, and he led investigations resulting in recovery of more than $280 million in government program funds.

Alissa D. Fleming, co-author of Chapter 28, is a Shareholder with Baker, Donelson, Bearman, Caldwell & Berkowitz, PC and co-leads the firm's Health Care Regulatory team. She represents large hospital systems, skilled nursing facilities, clinical laboratories, home health agencies, hospice providers, behavioral health providers, assisted living facilities, physicians, and health care professionals. Alissa focuses her practice on regulatory compliance; operations and risk management; Medicare and Medicaid reimbursement; Medicare and Medicaid audits and appeals; payor disputes and litigation; post-payment reviews; voluntary repayments; investigations and disclosures under the Centers for Medicare & Medicaid Services (CMS) and Office of Inspector General (OIG) self-disclosure protocols involving potential violations of the False Claims Act (FCA), Anti-Kickback Statute, and Stark Law; internal investigations involving allegations of health care fraud and retaliation under the FCA; disciplinary proceedings and peer review; confidentiality of medical information; facility licensing; certification of need; scope of practice; and wrongful death, professional negligence, professional licensing, and other health care issues involving state and federal law.

Caitlin Forsyth, co-author of Chapter 15, helps hospitals, clinics, and physician practices with a broad spectrum of health care regulatory compliance issues. Recent projects include advising on provider scopes of practice for licensed and unlicensed personnel, drafting plans of correction, auditing for compliance with price transparency requirements, and advising on reporting and refunding overpayments under the 60 Day Rule. She also regularly deals with federal and state licensure requirements, Medicare and Medicaid coverage and billing questions, and telehealth considerations.

Caitlin also serves as general regulatory counsel for several clinical, molecular, and toxicology laboratories. She provides advice on an array of issues implicating the regulatory regimes of CLIA, state laboratory licensing requirements, and the Stark Law and the Anti-Kickback Statute and the False Claims Act and state law counterparts. Recent projects including responding to requests for information from Medicaid Fraud Control Units, subpoenas and civil investigative demands from federal and state enforcement authorities, and medical record audits and overpayment demands from private payers. Caitlin enjoys working with clinical laboratories of all sizes and stages.

Larry Gage, co-author of Chapter 30, is Senior Counsel with Alston & Bird LLP. He focuses his practice primarily on public sector and nonprofit health law and policy, with a particular emphasis on governance. During his tenure as founding president of the National Association of Public Hospitals (now known as America's Essential Hospitals), Larry developed and achieved enactment of Medicare and Medicaid reimbursement reforms that are the economic lifeblood of hospitals serving a disproportionate number of elderly and low-income patients. America's Essential Hospitals has, for the last decade, called its annual member recognition awards program the Gage Awards.

Joseph V. Geraci, co-author of Chapter 31, is a partner with Husch Blackwell LLP. Joe began his legal practice as in-house counsel for a psychiatric hospital system, where he dealt firsthand with the challenges of health care operations that his clients faced. While home health agencies, physicians, hospitals and health systems focus on healing, Joe sorts through the nuts and bolts of their operations to help his clients make sense of the industry's complex regulations. He is board certified in health care law by the Texas Board of Legal Specialization and brings this in-depth background to his legal and business solutions. Joe's clients have come to rely on him to help resolve payment and reimbursement disputes and answer their compliance questions. He has created models to integrate physicians into larger healthcare systems and has guided home health agencies, physicians organizations, hospitals and health systems through the intricacies of mergers and acquisitions.

Dexter R. Golinghorst, co-author of Chapter 14, is an associate in the health care group at McDermott Will & Emery, LLP. He focuses his practice on regulatory and transactional health law matters including the Stark Law, Anti-Kickback Statute, EKRA and other fraud and abuse laws, billing and reimbursement, and Medicare and Medicaid enrollment matters. Dexter also assists in transactional matters, performing due diligence, drafting and reviewing provider agreements and providing counsel on compliance matters for mergers, acquisitions, joint ventures and other strategic transactions.

About the Authors

Adam H. Greene, co-author of Chapter 23, is a partner with Davis Wright Tremaine LLP. Adam specializes in health information privacy and security laws, using his experience as a former regulator to help clients understand how they can permissibly leverage their health data, bring their information security programs into compliance with the HIPAA Security Rule, and respond to potential breach incidents. He works with health care providers, health plans, cloud services providers, health IT companies, and financial institutions to navigate HIPAA and the patchwork of other federal and state health information laws. His work ranges from applying health information laws to new technologies, such as AI and machine learning, to working with organizations to analyze complex privacy and security incidents involving health data under federal and state breach notification laws.

Mary Grace Griffin, co-author of Chapter 28, represents clients across the health care industry on regulatory and compliance matters, including fraud and abuse and reimbursement issues, as well as various types of transactions and strategic affiliations. She provides guidance to health systems, hospitals, physician groups, behavioral health facilities, clinical laboratories, pharmacies, and other health care providers on federal and state issues relating to fraud and abuse, payment and reimbursement, compliance, licensure, certificate of need privacy and security, telemedicine, and medical staff issues. Mary Grace also advises on regulatory and structuring aspects of health care transactions and represents clients undergoing CMS, Joint Commission, EMTALA, and state surveys.

Stephanie Gross, co-author of Chapter 10, is a transactional and regulatory attorney whose knowledge of fraud and abuse law and managed care regulation allows her to help providers navigate a changing health care landscape. She frequently advises her clients on unique issues in the Medicare Advantage space and the regulation of value-based payment arrangements. She is a partner in the business department of Hooper, Lundy & Bookman, P.C., and is based in Los Angeles.

Pete Herrick, co-author of Chapter 33, has represented clients in complex and challenging transactions and antitrust litigation for nearly 20 years. Pete has tried numerous merger litigations to final judgments, both for and against the government, including groundbreaking cases on behalf of the Federal Trade Commission. In addition to representing clients on mergers and acquisitions across a range of industries before the FTC, Department of Justice, and other antitrust regulators, Pete leads high stakes antitrust litigation for clients in federal court. Clients trust Pete's strategic approach to both transactions and disputes, value his clear judgment, and depend on his credibility both in court and before the antitrust agencies.

Daniel J. Hettich, co-author of Chapter 9, is a partner in King & Spalding's Healthcare practice resident in Washington D.C. with a national practice focusing on complex Medicare reimbursement issues for hospitals. Dan provides his clients a comprehensive set of services from advising clients on Medicare requirements, to lobbying Congress when a change in statute is necessary. His deep understanding of Medicare reimbursement has allowed him to proactively identify Medicare reimbursement opportunities for his clients. Dan has developed particular expertise in litigating agency errors or misinterpretations of the law and has won multiple Federal court cases worth hundreds of millions of dollars. In 2021, Dan presented oral argument before the Supreme Court challenging a CMS policy that decreased payments to hospitals that treat a disproportionate share of indigent patients. Dan has been ranked by multiple national agencies including Chambers, Super Lawyers, Legal500, and Benchmark Litigation.

Stephanie M. Hoffmann, co-author of Chapter 13, is a Partner in the Healthcare Practice Group at Bradley. She serves clients in the health care industry on an array of regulatory, operational, and transactional matters, including hospitals, health systems, ambulatory surgical centers, long term care, and other provider types with mergers and acquisitions. Stephanie also advises clients on Medicare and Medicaid certification, compliance, and payment matters, as well as out-of-network balance billing laws and other issues affecting provider payment, including the No Surprises Act and the Hospital Price Transparency Rule. She has extensive experience helping clients navigate a variety of state and federal regulatory requirements, including facility licensure and the certificate of need application process.

John Holdenried, co-author of Chapter 34, is an attorney with Baird Holm LLP in Omaha, Nebraska. He provides a full range of health law services to health care providers, with a concentration on regulatory, transactional, and contracting issues; managed care contracting and network formation; tax exemption; and corporate compliance issues, including reimbursement, tax, Stark, and fraud and abuse. He received his undergraduate degree from Creighton University in 1972 and his law degree from the University of Michigan Law School in 1975.

Ann Hollenbeck, co-author of Chapter 25, is Partner-in-Charge in the Detroit office of Jones Day. She advises clients in the health care and life sciences industry on digital health, artificial intelligence, human subjects research, organ transplant, pharmacy/340B, and fraud and abuse matters. Ann also represents health care, life sciences, and technology companies, as well as ambulatory surgery centers and telemedicine providers, in such transactional matters as ancillary services and pharmacy arrangements, joint ventures, and physician-hospital relationships, including co-management arrangements. She regularly advises these entities with regard to the negotiation of clinical trial-related agreements,

including virtual clinical trials, in addition to related regulatory matters, such as Medicare reimbursement and institutional review board responsibilities.

Robert G. Homchick, co-author of Chapter 15, is a health care regulatory attorney who counsels clients in areas such as physician self-referral (i.e., the federal Stark Law and its state law counterparts), regulatory compliance, and fraud and abuse. Bob also regularly represents hospitals, physicians, ancillary services providers, and others in a wide variety of transactional matters including mergers, acquisitions and affiliations, and the formation and operation of joint ventures.

Louise Joy, co-author of Chapter 21, is a partner with Joy & Young LLP. She practices in the areas of health law, particularly Texas/Federal Administrative and Regulatory law and operational law issues as well as specializing in Medicare compliance, Medicare surveys, EMTALA enforcement and compliance, regulatory compliance with requirements for organ transplant programs, medical staff issues, Medicare/Medicaid provider enrollment, hospital operational issues, and psychiatric hospital operational and regulatory issues.

Joseph Keillor, co-author of Chapter 28, Of Counsel at Baker Donelson, represents health care clients in a broad range of regulatory and transactional matters. He regularly leads external compliance investigations, handles self-disclosures under the Self-Referral Disclosure Protocol (SRDP), and advises clients regarding the structuring or restructuring of contractual arrangements to minimize regulatory risks, especially with respect to the Physician Self-Referral Law and the Anti-Kickback Statute. Joseph regularly helps clients design and implement alignment strategies, including through developing Accountable Care Organizations (ACOs), along with a variety of other mechanisms. He also regularly advises clients regarding implications of changing payment models to their organizations and strategies for adapting to such changing models while managing regulatory risks.

Jason J. Krisza, co-author of Chapter 16, is a shareholder in the Corporate and Health Law groups at Wilentz, Goldman & Spitzer, P.A. He represents health care entities and individual health care professionals as well as businesses and business owners in a variety of legal disputes, business transactions, and regulatory matters affecting their operations. Jason's health care practice focuses on the representation of individual health care professionals, including physicians, dentists, physical therapists, nurse practitioners, pharmacists, physician assistants, and medical technicians, as well as medical practices, including hospital systems, ambulatory surgery centers, management services organizations, and clinically integrated networks. In connection with corporate law, Jason assists businesses and individuals in achieving their goals in all stages of a business' lifecycle, including formation, expansion, consolidation, and wind-down.

Sandi Krul, co-author of Chapter 36, is a shareholder at Hooper, Lundy & Bookman, representing hospitals and other health care providers and suppliers in a broad range of business transactions, including mergers and acquisitions, real estate transactions, financings and physician affiliations, and also advises clients on related regulatory compliance issues. She Co-Chairs her firm's Health Equity Task Force and DEI Committee and is a former Chair of the AHLA Real Estate Affinity Group.

Michael S. Lemell, JD, LLM, MBA, CSPR, LSSGB, co-author of Chapter 29, serves as the Director of Value-Based Care Contracting at AdventHealth, a leading national non-profit health system. In this role, Michael focuses on advancing the health system's value-based care strategies across Medicare Advantage and Commercial payors. His expertise in aligning health care delivery with value-based principles plays a pivotal role in ensuring quality care and cost efficiency across the organization. Through his leadership, Michael is dedicated to transforming health care to meet the evolving needs of patients and providers alike.

Amy Lerman, co-author of Chapter 24, chairs Epstein Becker Green's Telehealth Practice. Amy supports telehealth clients as they develop and execute strategies for company structure, development, and growth. Amy also advises telehealth clients on trends and the development of regulatory strategies for growing and expanding telehealth businesses to achieve nationwide footprints. Broadly, Amy also works with clients on matters involving government investigations, audits, and related claims of fraud, false claims, and other noncompliant behaviors, as well as in the context of evaluating and developing corporate compliance programs and infrastructures.

Jeffrey Lin, co-author of Chapter 6, was a regulatory associate who advised providers on Medicare reimbursement in Hooper Lundy & Bookman's San Francisco office until September 2023. Currently, he is an attorney at the U.S. Department of Health & Human Services, Office of General Counsel. The views of the sections of the chapter edited by him are his own and do not necessarily reflect those of the U.S. Department of Health and Human Services or the United States Government.

Tony R. Maida, co-author of Chapter 14, is a partner at McDermott Will & Emery, LLP in the New York office and Co-Leader of the firm's Healthcare Regulatory and Compliance Practice Area. Tony counsels health care and life sciences clients on government investigations, regulatory compliance and compliance program development and has extensive experience in health care fraud and abuse and compliance issues, including the federal and state Anti-Kickback and Physician Self-Referral Laws and Medicare and Medicaid coverage and payment rules. Prior to McDermott, Tony served

as Deputy Chief of the Administrative and Civil Remedies Branch Office of Counsel to the Inspector General at the United States Department of Health and Human Services.

Wendy Maneval, author of Chapter 19, has been on forefront of developments in health law, health policy and institutional advancement. She has extensive experience representing diverse health care organizations on legal, regulatory, compliance and business matters, and assisting with strategic planning. She currently serves as the Chief Legal/Risk and Privacy Officer of Eagleville Hospital, a behavioral health hospital in Norristown, Pennsylvania. Prior to joining Eagleville, she was in-house counsel at the Christiana Care Health System in Delaware and at the Devereux Foundation in Villanova, Pennsylvania. Among her many publications and presentations, she was primary author of a two-volume treatise, Health Law and Litigation in Pennsylvania and New Jersey. She received her J.D. degree from Temple University School of Law, and a B.A. from the University of Pennsylvania.

Ross D. Margulies, co-author of Chapter 11, is a partner with Manatt, Phelps & Phillips, LLP. Ross focuses on complex federal and state health care and life sciences legal and regulatory matters, with a special expertise in Medicare and Medicaid law. He advises biopharmaceutical companies, providers, payers, and others in the health care space on novel coverage, reimbursement, and compliance issues, as well as in navigating the Federal and state health care legislative and regulatory landscape. Ross is a frequent speaker at industry events, where he has gained a reputation as a leading authority on a number of critical programs, including the 340B Drug Pricing Program and the Medicare Drug Price Negotiation Program enacted as part of the Inflation Reduction Act in 2022.

Jason T. Mayer, co-author of Chapter 12, is a partner with Reed Smith LLP. Jason counsels managed care organizations in arbitrations and litigation in state and federal courts across the country. He has extensive experience handling payer/provider disputes, including assisting clients with a wide variety of contract claims, out-of-network reimbursement issues, claims related to fraud, waste, and abuse, and alleged violations of state and federal statutes and regulations. Jason represents commercial clients as well as Medicare Advantage and Medicaid managed care organizations, providing counsel on unique litigation and compliance issues across various markets and regulatory spheres.

Lyndsay Medlin, co-author of Chapter 17, is Counsel with Bradley Arant Boult Cummings LLP, where she assists clients across industries with litigation, internal investigations, and compliance needs. Lyndsay is skilled in every step of an investigation, from developing a comprehensive investigative plan at the outset, counseling clients on potential risks, interviewing employees, negotiating with government entities, and creating effective e-discovery strategies to respond to government subpoenas and requests and whistleblower complaints. When clients require an advocate in the courtroom, Lyndsay is also experienced with litigating and arbitrating cases, and she works closely with clients to learn what matters to their businesses to best protect those interests nationwide.

Elizabeth Mills, co-author of Chapter 34, recently retired from the practice of law after 38 years at McDermott Will & Emery, Proskauer Rose, and in solo practice. She concentrated her practice on regulatory and transactional issues and tax exemption issues for health care organizations as well as a wide variety of other types of exempt organizations. Elizabeth received her law degree from Northwestern University School of Law, her undergraduate degree from the University of Kansas, and a master's in health care policy and management from the Harvard School of Public Health.

Goran Musinovic, co-author of Chapter 36, is Senior Vice President and General Counsel with Realty Trust Group. He serves as the leader of RTG's Compliance Service Line, providing a broad spectrum of real estate compliance advisory services, which range from helping health systems create, improve and implement effective real estate compliance programs to minimize their exposure under The Stark Law, The Anti-Kickback Statute, and The False Claims Act to providing fair market value and commercial reasonableness analyses in connection with various real estate arrangements and transactions. Additionally, Goran serves an integral role on RTG's health care real estate development projects by creating and implementing legal frameworks for those projects. He also serves as the firm's general counsel and is responsible for the overall risk management for all of the firm's services lines and the firm in general.

Robert R. Niccolini, co-author of Chapter 35, is a shareholder in the Washington, D.C. office of Ogletree Deakins, and served as the co-chair of the firm's Healthcare Industry Group for almost a decade. He is the only labor and employment lawyer to have served as President of the American Health Law Association, and is a Fellow of both the AHLA and the College of Labor and Employment Lawyers. He represents management in employment litigation and labor disputes, with special experience in the health care, technology, and government contracting industries, and his practice includes all facets of employment discrimination, harassment, wage and hour, ADA, FMLA, covenants not to compete and employment torts, as well as labor arbitration, union campaigns and unfair labor practice proceedings. He also has extensive experience with class and collective actions.

Mark Ogunsusi, co-author of Chapter 8, is an associate with Powers, Pyles, Sutter and Verville, P.C., where he regularly advises an array of health care entities on the nuances of the 340B program, the Medicaid drug rebate program, federal pharmacy law, food and drug law, and state pharmacy law. Mark has significant experience in all aspects of the 340B program, including covered entity registrations, contract pharmacy arrangements, patient eligibility determinations,

duplicate discount issues, drug inventory management, eligibility requirements, third party vendor arrangements, auditable records requirements, and other 340B program compliance matters.

Mark has more than 10 years of experience as a pharmacist, which inform his health law practice. His other relevant prior experience includes serving as the CEO of PrystM LLC, a health care and technology consulting firm. Before attending law school, he worked in several different health care settings, including years of service at one of the nation's largest safety-net hospitals. Mark is a fervent advocate for promoting access to pharmaceutical care and supporting the nation's safety-net providers. He is a co-author of "340B Drug Pricing Program," a chapter in the Health Care Compliance Association's *2021 Complete Healthcare Compliance Manual*. Mark earned his J.D. from Georgetown University Law Center and graduated *cum laude* with a doctorate of pharmacy from Mercer University College of Pharmacy.

Karen R. Palmersheim, co-author of Chapter 12, is Senior Managing Counsel for Cigna legal. She oversees legal support for the national US Commercial Medical Network team and also provides direct provider network support for the Southeast region. Prior to Cigna, Karen was a health care litigation Partner with Locke Lord. Karen has frequently published articles in health care publications and has been a regular speaker at AHLA and other health care conferences and webinars. She was a faculty member for the National Institute for Trial Advocacy for eight years, teaching other lawyers deposition skills in three-day workshops. She currently serves on the Planning Committee for the Institute for Health Plan Counsel Program, and previously served as Vice Chair of Membership for the American Health Care Lawyers Association's Payers, Plans and Managed Care Practice Group, and the Chair of the Health Plan Affinity Group. Karen is also a member of the Board of Directors for Sycamores, and has previously served on the board of the Pasadena Tournament of Roses Foundation, Barlow Respiratory Hospital Foundation, Leadership Pasadena, and the Redstone Foundation for Ageless Living, for which she served as Chair. Karen also serves as Chair for the Pasadena Tournament of Roses.

Arthur E. Peabody, co-author of Chapter 6, practices health care law with a focus on reimbursement as of Counsel in the Washington, D.C. office of Hooper, Lundy & Bookman, PC. He represents hospitals and other health care providers and has many years of experience litigating health care disputes, including Medicare reimbursement issues. Previously, Arthur served as a career trial lawyer in the United States Department of Justice where he held high level executive positions in the Civil Rights Division and served as an Assistant United States Attorney for the Eastern District of Virginia (Alexandria). In addition, he has served in a number of federal bankruptcy cases as the Patient Care Ombudsman. In his years of practice, Arthur has addressed most legal issues that arise in the health care arena. He has written widely on health care issues, has appeared on numerous panels at meetings of the American Bar Association and the American Health Law Association, and is a member of the American Arbitration Association's Panel of Health Care Mediators and Arbitrators.

Michael W. Peregrine, author of Chapter 32, represents corporations, their boards of directors, and individual directors and officers in connection with the full range of governance, fiduciary duty, director liability and leadership issues. Much of Michael's practice involves advising boards of directors on matters of sensitivity and controversy, often in connection with corporate and fiduciary crises. He is recognized as one of the leading national corporate governance counselors and is a respected interpreter of the law of fiduciary duties.

Michael serves as outside governance counsel to many prominent corporations, including hospitals and health systems, voluntary health organizations, colleges and universities, disease charities, social service agencies, health insurance companies, pharmaceutical companies and financial institutions. Clients regularly seek Michael's advice on complex and discreet governance matters.

Alek Pivec, co-author of Chapter 9, is an associate in the Washington, D.C. office of King & Spalding and a member of the firm's Healthcare practice. Alek specializes in representing hospitals and other healthcare providers in reimbursement controversies involving government payors such as Medicare and Medicaid.

Caroline Reignley, co-author of Chapter 7, is a Partner at McDermott Will & Emery, where she provides regulatory and compliance counsel to for-profit and nonprofit hospitals, health systems, and other health care providers as well as life sciences and technology companies. Caroline advises providers, consultants, and vendors on a wide range of business, legal, and regulatory issues. She has extensive experience advising clients on Medicare and Medicaid regulatory requirements including enrollment, participation requirements, and reimbursement. She also advises clients on professional licensure, scope of practice, and physician and health care professional clinician relationships and supervision, together with overall corporate compliance.

Brad Robertson, co-author of Chapter 17, is a partner at Bradley Arant Boult Cummings LLP, where he works with clients facing government investigations and litigations, dealing with whistleblower allegations and *qui tam* actions, and planning compliance programs to prevent these occurrences in the first place. Whether necessitated by an employee raising compliance concerns, a visit from a government agent, or the receipt of an investigatory subpoena, Brad conducts

confidential internal investigations for his clients to determine whether and where liability exists. He helps his clients navigate compliance and potential liability under the False Claims Act and Anti-Kickback Statute, in addition to other areas of health care fraud and abuse law. Brad received his law degree with honors from the University of Chicago.

Robert L. Roth, co-author of Chapter 6, founded the Washington, D.C., office of Hooper, Lundy & Bookman, P.C., the largest health law-only boutique in the United States. Bob formerly served as a senior attorney for the Centers for Medicare & Medicaid Services of the U.S. Department of Health and Human Services and as an Assistant Attorney General for the State of Maryland. He actively counsels and represents in litigation clients on payment and compliance issues arising under the Medicare and Medicaid programs. Bob is one of the select few health lawyers to have argued before the United States Supreme Court, which he did in *Sebelius v. Auburn Regional Medical Center*, 133 S. Ct. 817 (2013). A frequent speaker and author on health law topics, Bob formerly was Co-Chair of the Program Committee for AHLA's Institute on Medicare & Medicaid Payment Issues Conference and was an Adjunct Professor at the University of Baltimore School of Law from 1984 through 2015. Ranked by clients and peers as one of the leading health care attorneys in Washington, D.C. by *Chambers USA*, Bob was described as "zealous and committed," as "stand[ing] out as having second-to-none knowledge of Medicare Secondary Payer issues," and as being "very responsive, very efficient and cuts to the chase."

Deborah Samenow, co-author of Chapter 9, is Of Counsel in the health care regulatory practice at DLA Piper LLP (US). She concentrates her practice on complex health care regulatory matters, with special focus on reimbursement disputes and audits with federal and commercial payers as well as enrollment and compliance matters. Deborah has more than a decade of federal government experience reviewing and adjudicating Medicare claims for coverage and reimbursement. She has drawn on that experience to help advise clients on provider enrollment and reimbursement issues, licensure matters, overpayment disputes, and related regulatory matters such as those associated with internal and external audits, due diligence analyses, compliance plans, claim appeals, and billing and coding issues. She assists clients on effectively navigating regulatory hurdles and managing risk so that they can focus on patient care.

Michael F. Schaff, co-author of Chapter 16, is shareholder with Wilentz Goldman & Spitzer and co-chair of the corporate, health care and cannabis departments. Schaff is a Fellow of the American Health Law Association (AHLA), a recipient of the Greenburg Founders Award and a past Director, and Program Chair of both the Physician & Hospital Law Institute and the Fundamentals of Health Law Program. Michael is a prolific speaker and author on numerous health law topics. In addition to his undergraduate and law degrees, Michael has an MBA (specializing in Finance) and an LL.M. (Taxation).

Alaap Shah, co-author of Chapter 24, co-chairs Epstein Becker Green's Privacy, Cybersecurity and Data Asset Management Practice. He uses tech-savvy and solutions-oriented approaches to deftly guide clients through complex and ever-evolving privacy, cybersecurity, medical device, artificial intelligence (AI), interoperability, digital health, telehealth, and other laws and regulations. Alaap represents providers, payors, biopharma companies, health information technology companies, AI companies, data analytics companies, health information exchanges and other innovative companies to build and maintain trust in the health care ecosystem.

Jacob S. Simpson, co-author of Chapter 25, a partner at Breazeale, Sachse & Wilson, L.L.P., is a Board-Certified Health Law Specialist recognized by the Louisiana Board of Legal Specialization. With a five-year tenure as Chair of the Louisiana State Bar Association Health Law Section, Jacob brings extensive expertise to the clinical research industry. His services encompass reviewing complex contracts, negotiating for hospitals, academic medical centers, and IRBs, and facilitating access to experimental treatments for Louisiana residents. As a former in-house counsel at an academic medical center, Jacob offers valuable insights into FDA and Office of Human Research Protection (OHRP) regulations, including patient consent, tissue usage, and the IRB process. Jacob's collaborative efforts extend to large academic medical centers across Louisiana and the nation, where he provides guidance on human subject research laws. Notably, he has served on the IRB for a major regional hospital and an Air Force clinical research laboratory. Before his legal career, Jacob earned a degree in Microbiology with a minor in Chemistry from Louisiana State University, where he engaged in biomedical research at the Pennington Biomedical Research Center.

Heather H. Sveadas, co-author of Chapter 13, serves as Deputy General Counsel for ApolloMD, a private, independent group that provides integrated, multispecialty physician, APC, and practice management services. She has extensive experience representing health care organizations, including health systems, health care providers, and managed care organizations on operational, regulatory, and managed care related matters. As in-house counsel, Heather focuses on various health care payment issues, including managed care contracting, payer disputes, the No Surprises Act, and navigating the independent dispute resolution process. She received her J.D. Degree from Emory University School of Law and a B.A. from Emory University.

Regan Tankersley, author of Chapter 5, is a shareholder with the law firm Hall Render with a 20+ year career focusing on health care regulatory and payment policy matters. Regan advises a variety of health care clients, including hospitals,

health systems, physician practices, IDTFs, clinical labs, telehealth providers and ASCs, in the areas of regulatory compliance, billing and reimbursement, and coverage and payment policy.

Adrienne A. Testa, co-author of Chapters 1 through 4, an associate with Polsinelli, provides counsel to a variety of health care providers, including hospitals and health systems, home health and hospice agencies, individual health care professionals, pharmacies, and physician groups. She leverages her prior in-house experience and deep knowledge of health care law to provide clients with effective, efficient, and innovative legal solutions. Adrienne regularly supports health care providers through transactional matters including mergers, acquisitions, joint ventures, and reorganizations.

Bruce J. Toppin, author of Chapter 20, has served as chief legal officer for North Mississippi Health Services since 1996. He previously worked as a partner with Jones, Walker in New Orleans. He is licensed to practice law in Louisiana and Mississippi. Bruce received a Bachelor of Arts degree in political science from the State University of New York at Albany, a juris doctor degree from Loyola University School of Law in New Orleans, and a master's degree in health administration from the University of Alabama at Birmingham. He has presented at numerous AHLA meetings over the past 28 years.

Vincent Torres, co-author of Chapter 27, joined the University of Miami in 2014, where he currently serves as the Emergency Management Director for UHealth & Miller School of Medicine. In this role, Vincent supervises a team of emergency management professionals to mitigate risk and ensures the resiliency of the only academic health system in South Florida with three hospitals and mix of over 40 outpatient clinics, ambulatory surgical centers, academic, research, and administrative facilities spread across four counties on the east and west coasts of Florida. Vincent also serves as the Associate Director of Disaster Management for the University's Global Institute for Community Health and Development where he supports domestic and international communities through training, exercise, and emergency response. Since 2004, Vincent has responded to, supported and managed various aspects of major emergency incidents, disasters, large scale special events and countless trainings and exercises. Throughout his career, Vincent has held various positions in the public and private sectors (Primarily working to protect critical infrastructures) in the fields of law enforcement, corporate security, and emergency management. Vincent is a certified Crisis Intervention Team (CIT) Deputy and a Certified Healthcare Preparedness Professional (CHEP) by the International Board for Certification Services and Management (IBCSM).

Cori Casey Turner, co-author of Chapter 31, is Senior Counsel to Husch Blackwell LLP. Cori advises health care clients such as academic medical centers, children's hospitals, and CLIA-certified laboratories on complex regulatory compliance and reimbursement-repayment matters, as well as contractual issues, strategic affiliations, and leadership transitions. She also represents health care providers in civil and criminal fraud investigations and self-disclosures. She is known for excellent client service and personalized support.

David J. Vernon, co-author of Chapter 6, is the Managing Partner of the Washington, D.C. Office at Hooper, Lundy & Bookman, P.C., where he specializes in Medicare and Medicaid reimbursement, especially on Graduate Medical Education, Medicare Area Wage Index, and rural floor issues. A widely recognized licensure and certification expert, David also advises clients on complex regulatory issues that arise in the context of mergers, acquisitions, reorganizations, and related transactions. David holds a J.D. from the University of California, Berkeley School of Law.

William H. von Oehsen III, co-author of Chapter 8, is a Principal in Powers, Pyles, Sutter and Verville, P.C., a law firm specializing in health care law and policy. Mr. von Oehsen has more than 30 years' experience on pharmaceutical pricing and reimbursement matters, including the 340B drug discount program, the Medicaid drug rebate program, Medicare Part D, Robinson-Patman, and state Medicaid and pharmacy laws. He helped establish and serves as outside counsel to 340B Health, an advocacy organization of over 1,400 public and private non-profit hospitals participating in the 340B program. Mr. von Oehsen played a key role in helping to enact the 340B program in 1992, as well as to expand the law in 2010 under the Affordable Care Act.

In addition to representing clients on 340B matters, Mr. von Oehsen provides guidance to pharmacies, pharmacy-related vendors and consultants, states, local governments, and other health care entities in their efforts to improve access to pharmaceutical care and to ensure compliance with drug pricing laws. He received a Bachelor's degree from Princeton University, an M.T.S. from Harvard University, and a J.D. from Georgetown University.

Jody Ward-Rannow, co-author of Chapter 35, is Of Counsel to Ogletree Deakins, where she currently represents large corporate clients and small local businesses in matters involving all aspects of labor and employment law, including disability, race, and gender/pregnancy discrimination claims; retaliation claims; Family and Medical Leave Act (FMLA) claims; workers' compensation retaliation claims; noncompete/nonsolicitation, and unfair competition claims; breach of contract claims; and whistleblower retaliation claims. Additionally, Jody regularly partners with HR professionals, business leaders, and/or in-house legal counsel to advise on a variety of employment issues, including employee discipline and termination, discrimination and retaliation claims, employee relations, policy drafting and revisions, supervisor training, Minnesota affirmative action reporting requirements, FMLA administration, wage and commission

payment requirements, drug testing policies, employee privacy, and other federal and state employment law issues.

David A. Weil, co-author of Chapter 30, is the Vice President-Legal for 360 Health MSO, LLC, 360 Anesthesia PLLC, and their affiliates and provides legal services to various business law clients. David served as Vice President, Legal Services, Quorum Health Corporation (QHC), Quorum Health Resources (QHR) and Quorum Purchasing Advantage (QPA), Brentwood, Tennessee. He served Community Health Systems as Vice President & Associate General Counsel of Divisions 2, 1, and then 4 and then Vice President, Legal Services, assigned to QHR and QPA. After being focused on health care operations, regulatory compliance, and transactions, David's assignment to QHR and QPA grew his confidence in the effective application of his skills and substantially broadened his scope of practice as a business lawyer. He was afforded opportunities and encouraged to lead not only teams of lawyers to resolve disputes and negotiate transactions, but also multi-disciplinary teams to achieve significant and measurable results across a broad spectrum of subject matter areas. David's tenure with this family of companies lasted 10.5 years. He proudly served as Operations Counsel and then Vice President & Chief Legal Officer of five divisions within the state of Florida for HCA Healthcare for 12.5 years. David started his career as a health lawyer at Buckingham, Doolittle & Burroughs in Akron, Ohio, where he grew up, and he earned his Juris Doctor and Master of Business Administration in Management at The University of Akron.

Tracy Weir, co-author of Chapter 9, is a Partner in the health care regulatory practice at DLA Piper LLP (US). Tracy concentrates her practice in the areas of health care reimbursement, compliance, and HIPAA. She counsels a wide variety of clients on matters relating to Medicare and Medicaid enrollment and participation, conditions of payment and coverage, payer audits, claims appeals, billing and coding, overpayments and refunds, revocations, compliance programs, compliance audits and investigations, and HIPAA compliance. She routinely represents clients in matters before the Centers for Medicare and Medicaid Services, in administrative litigation before the Office of Medicare Hearings and Appeals, and in matters before the Office for Civil Rights.

Barbara Straub Williams, co-author of Chapter 8, is a health care attorney at Powers Pyles Sutter & Verville focusing on a wide range of federal and state regulatory programs. Barbara regularly advises clients on compliance with the requirements of the 340B drug discount program and on preparing for, and responding to, 340B audits, making disclosures to OPA and manufacturers, and advising on registration and recertification issues.

Barbara's practice also focuses on Medicare and Medicaid reimbursement issues, both in advising clients on meeting regulatory requirements and representing clients before the Provider Reimbursement Review Board. She has obtained favorable decisions at the Board on Medicare reimbursement disputes involving wage index, indirect graduate medical education payments, and the Hospital Inpatient Quality Reporting Program. She has also successfully settled administrative cases involving disproportionate share hospital and bad debt issues. In addition, Barbara counsels clients on Medicaid reimbursement issues, including Medicaid disproportionate share and waiver issues.

Cynthia F. Wisner, author of Chapter 18, has represented hospitals, health care systems, physician groups, nonprofits, and other health care organizations since graduating from University of Michigan Law School in 1981. Cindy recently retired as associate counsel in the legal department of Trinity Health, one of the largest Catholic health care systems in the country. At Trinity Health she supported the compliance, revenue excellence, and information technology departments and specialized in reimbursement, hospital-physician relationships, regulatory compliance, health information technology, privacy, security and HIPAA, Medicare appeals, kickback and self-referral (Stark) prohibitions, and government investigations. Cindy previously worked at several prestigious Detroit law firms. Prior to joining Trinity Health, she served five years as general counsel to the Detroit Medical Center. She has completed terms on the board and as chair of the in-house counsel practice group of the American Health Law Association (AHLA), served for six years as editor-in-chief of AHLA's "Journal of Health and Life Sciences Law," and is co-editor of the AHLA compliance manual.

Virginia Wright, co-author of Chapter 17, is an associate at Bradley Arant Boult Cummings LLP, where she practices with the Government Enforcement and Investigations Practice Group.

Jeff J. Wurzburg, co-author of Chapter 10, is a health care regulatory attorney at Norton Rose Fulbright. He focuses his practice on regulatory, compliance, reimbursement and policy issues facing providers and health plans, with vast experience in Medicare, Medicaid and the Affordable Care Act. He regularly advises clients on federal health care program reimbursement, compliance, billing and reimbursement disputes, state and federal fraud and abuse laws, and government investigations. Jeff previously served as an attorney in the U.S. Department of Health and Human Services Office of the General Counsel in Washington, D.C., where he advised the Centers for Medicare & Medicaid Services and the Center for Medicare and Medicaid Innovation. He advised on a wide-ranging portfolio that included Affordable Care Act regulations, guidance and litigation and the development and testing of innovative health care payment and service delivery models. Jeff serves on the State Bar of Texas Health Law Section Council and the American Health Law Association Health Plan Law and Compliance Institute Planning Committee. He is the Chair of the American Bar Association Health Law Section Managed Care Interest Group and a Co-Chair of the Programs Executive Committee. He

serves on the Board of Directors for the Multi-Assistance Center at Morgan's Wonderland, is a Director of The Health Cell, and is a graduate of Leadership San Antonio, Class 45.

Hilary Young, co-author of Chapter 21, is a partner of Joy & Young, L.L.P., in Austin, Texas. Ms. Young practices in the regulatory, licensing, and administrative areas of health law, and is board certified in Health Law by the Texas Board of Legal Specialization. She advises institutional health care providers on compliance with various state and federal laws, including the Emergency Medical Treatment and Labor Act (EMTALA), and she defends providers in government surveys and administrative enforcement actions. Ms. Young is admitted to the State Bar of Texas and the United States Court of Appeals for the Fifth Circuit. She is an active leader in the American Bar Association Health Law Section and a member of the American Health Law Association. Ms. Young earned her J.D. from the University of Texas School of Law, an M.A. in Latin from the University of Oklahoma, and an A.B. in Latin and History, *cum laude*, from Duke University. Before entering private practice, Ms. Young served as a law clerk for the late Jerre S. Williams, Senior Judge for the United States Court of Appeals for the Fifth Circuit.