

## About the Editors

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**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. Scheutzw** 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 Council, and member of the Quality Council. Claire has also contributed to AHLA as an author and speaker at in-person programs, webinars, and podcasts.

# About the Authors

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**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.

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**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

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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

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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.

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**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,

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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, LL.M., 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

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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.

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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.

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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.

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