About the Editors

Ann T. Hollenbeck is a Partner in the Health Care and Life Sciences Practice of Jones Day. She advises hospitals, physicians, and other providers on the implications of health care reform, human subjects research matters, and fraud and abuse. She represents academic medical centers and health systems on clinical affiliations, 340B program matters and physician compensation. Ann also advises health care entities on transactional matters such as ancillary services arrangements, joint ventures, and physician-hospital relationships. She regularly represents health care entities on clinical trial-related agreements and related regulatory matters, including subject recruitment and informed consent. She received her undergraduate degree from Butler University and her law degree from Indiana University School of Law, and is licensed to practice law in Michigan, Indiana, and Illinois.

Karen Lovitch is the Chair of the Health Law Practice at Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, PC. She counsels health care clients on regulatory, transactional, and operational issues, including Medicare coverage and reimbursement, the development and implementation of health care compliance programs, and licensure and certification matters. In addition, Ms. Lovitch advises clients on the legal, practical, and fraud and abuse implications of business arrangements and sales and marketing practices. Her experience includes matters related to the Anti-Kickback Statute, the Stark Law, state statutes prohibiting kickbacks and self-referrals, and the federal Physician Payments Sunshine Act.

Lester J. Perling is a partner at Nelson Mullins Riley & Scarborough LLP. Mr. Perling is a board-certified health law attorney with extensive experience in compliance, enforcement, and reimbursement matters. Mr. Perling's practice focuses on advising health care providers of all types with regard to complying with federal and state laws, with emphasis on Stark Law and reimbursement/billing compliance. He represents providers when they are the subject of government and private payer audits, including the appeals of audit findings, as well as federal and state administrative, civil, and criminal investigations pertaining to health care fraud and abuse. He also advises health care clients with regard to regulatory compliance in the context of transactions and business structures. Mr. Perling has more than ten years of experience as a health care executive. He is a past adjunct faculty member at Florida International University, and has also taught courses at Florida Atlantic University and Nova Southeastern University School of Business and Entrepreneurship. Mr. Perling is a regular speaker on compliance, regulatory, and enforcement matters for various state and national organizations.

Cynthia F. Wisner (Author Chapter 2, Chapter 3) has represented hospitals, health care systems, physician groups, nonprofits and other health care organizations since graduating from University of Michigan Law School in 1981. She is associate counsel in the legal department of Trinity Health, one of the largest Catholic health care systems in the U.S. Ms. Wisner supports the system office information technology services, revenue excellence, and compliance departments. She specializes in reimbursement; hospital-physician relationships; health care regulatory compliance; health information technology purchases, privacy, security, and HIPAA; Medicare individual and group appeals; kickback and self-referral (Stark) prohibitions; and government investigations. Prior to joining Trinity Health, Ms. Wisner worked at several prestigious Detroit law firms. In 1994 she became General Counsel to The Detroit Medical Center where she advised the community health care system for five years prior to joining Trinity Health. She has completed terms on the Board and as Chair of the In-House Counsel Practice Group of the American Health Lawyers Association (AHLA). She served six years as the Editor-in-Chief of AHLA's *Journal of Health & Life Sciences Law*, and is co-editor of this Manual.

About the Authors

Brooke Bennett Aziere (Chapter 14, Medical Necessity, Claims, and Payment Processes) is a partner in the Wichita, Kansas office of Foulston Siefkin LLP. Ms. Aziere is a member of the firm's health care practice group and current practice group leader. Her major practice areas include health care regulatory matters, HIPAA, HITECH, compliance, senior care, risk management, Medicare & Medicaid reimbursement, and government investigations relating to fraud and abuse. She has frequently represented clients in matters before state licensing boards, and other clients in state and federal lawsuits involving a variety of cases, including medical malpractice defense, intellectual property disputes, contract disputes, and torts. She is a 2003 graduate of the University of Kansas School of Law, where she was a member of the Order of the Coif and an articles editor for the *Kansas Law Review*. Ms. Aziere also received the Faculty Award for Outstanding Scholastic Achievement. She is a member of the Kansas and Texas Bar Associations, the American Health Lawyers Association, and the Kansas Association of Hospital Attorneys. Ms. Aziere is licensed to practice in Kansas and Texas.

Amy Bailey (Chapter 13, Internal and External Audit Basics) CHC, CPC, COC, CPC-I, CCS-P is a Principal with HBE Advisors LLC and has over 20 years of health care experience and specializes in regulatory compliance for coding and billing with emphasis in documentation, coding and billing reviews; independent review organization services, due diligence and risk assessment reviews; internal investigations; and litigation support services. Ms. Bailey has extensive experience working with publicly traded health care companies, large hospital systems, law firms, and physician group practices. Ms. Bailey's experience ranges from handling routine compliance issues to provider defense of government false claims and fraudulent coding and billing cases. Ms. Bailey is certified in Healthcare Compliance and is also a certified coder for both physician and hospital coding, and an approved coding instructor for the American Academy of Professional Coders. She has taken many leadership roles in the industry, including currently serving as an Auditing and Monitoring Tools Editorial Board Member for the Healthcare Compliance Association and is also a former Regional Governor and Examination Committee Chair American College of Medical Coding Specialists. Ms. Bailey has published articles featured in *Compliance Today* and *Health Lawyers Weekly*. She has also been selected as a speaker for groups including the American Health Lawyers Association, American Academy of Professional Coders, Healthcare Compliance Association, Georgia Hospital Association, Idaho Medical Group Management Association, and the Idaho Association of Home Care.

Douglas A. Blair (Chapter 15, Stark and Anti-Kickback Prohibitions) currently serves as Director of Legal Services for BJC HealthCare in St. Louis, Missouri, where he is the primary counsel for several hospitals, as well as BJC's real estate, construction, and supply chain departments. BJC HealthCare is one of the largest nonprofit health care systems in the U.S. At BJC, Mr. Blair counsels his clients on a wide variety of matters, including fraud and abuse, privacy and confidentiality, medical staff issues, and complex corporate transactions. Mr. Blair is the author of a number of law journal and professional newsletter articles pertaining to health law-related topics. He is a graduate of Cornell University (BA), Indiana University-Bloomington (JD *cum laude*), St. Louis University (LLM in Health Law), and Webster University (MHA and MBA, both with Academic Honors). Mr. Blair is admitted to practice in Missouri and California.

Elizabeth Callahan-Morris (Chapter 18, Health Information Privacy and Security Laws) serves as Vice President & Deputy General Counsel, Hospital Operations, for Henry Ford Health System. Previously, she was a Shareholder with Hall Render, a national health law firm. Ms. Callahan-Morris focuses her practice in the areas of regulatory compliance, fraud and abuse, patient care, and privacy and security matters. She has advised health care clients on state, federal, and international confidentiality laws, "big data" sharing, data breach reporting, and internal and governmental investigations. Ms. Callahan-Morris is a frequent speaker on privacy and security topics and has been recognized in Best Lawyers in America, as a Top Lawyer in DBusiness Magazine, and as a Fellow of the State Bar of Michigan Health Care Law Section. She is a graduate of Michigan State University (1993) and The George Washington University Law School (1996).

Kyle E. Calvin (Chapter 14, Medical Necessity, Claims, and Payment Processes) is an associate in the Wichita, Kansas office of Foulston Siefkin LLP. Mr. Calvin advises hospitals, physician groups, and other providers on a broad range of health care regulatory and compliance matters. His practice also includes the formation of new health care entities, the purchase and sale of real estate, and commercial space leasing. Mr. Calvin graduated 1st in his class from Washburn University School of Law in 2017. He is a member of the Kansas Association of Hospital Attorneys and the Kansas Bar Association.

Elizabeth Carder-Thompson (Chapter 22, Drugs, Devices, and Life Sciences Entities) is a Senior Counsel in the Washington, DC office of Reed Smith LLP, and has been practicing health care law for over 35 years. Ms. Carder-Thompson represents a variety of manufacturers, associations, and individual providers and suppliers of health services, including hospitals, physicians, pharmaceutical and device manufacturers, hospices, medical equipment suppliers, long-term care facilities, home health agencies, and suppliers of diagnostic, laboratory, and other services, as well as financial services firms that support the health care industry. Her specific areas of responsibility in the life sciences area include coding, coverage, and reimbursement, fraud and abuse counseling and representation, and regulatory, legislative, and enforcement issues, primarily involving Medicare, Medicaid, and third-party payers. She is Past President of the American Health Lawyers Association, and an AHLA Fellow. She graduated *magna cum laude* from Brown University, where she was elected to Phi Beta Kappa, and from the College of William & Mary School of Law.

Ritu Kaur Cooper (Chapter 1, Glossary of Key Terms) is a Shareholder in Hall Render Killian Heath & Lyman, PC's Washington, DC office and is a member of the firm's health counsel section. Her practice consists of representing health care providers such as hospitals, health systems, laboratories, dialysis facilities, large physician practice groups, and medical device companies in False Claims Act litigation, regulatory, and compliance matters with a particular focus on fraud and abuse and compliance as well as internal and government investigations. Ms. Cooper served as General Counsel for Capital Clinical Integrated Network, a care coordination entity providing the DC Medicaid population with care coordination services. She currently serves as Interim Chief Compliance for Beaver Dam Community Hospitals, Inc. Ms. Cooper is licensed to practice in New Jersey, Pennsylvania, Missouri, and the District of Columbia. She is also admitted before the United States Supreme Court and the District Court of the District of New Jersey. Ms. Cooper is an honors graduate from The George Washington University (BA), a *cum laude* graduate from Syracuse University (JD), and was awarded an LLM in Health Law by Saint Louis University. Ms. Cooper served as the American Health Lawyers Association's Vice-Chair of Research and Website for the Hospitals and Health Systems Practice Group for four years. She is now Vice-Chair of Strategic Planning and Special Projects. She is also the Immediate Past President of the South Asian Bar Association of Washington, DC.

Thomas S. Crane (Chapter 12, Repayments and Self-Disclosures) is a Member at Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, PC and practices in the Health Law Section and the firm's Health Care Enforcement Defense practice group in both its Boston, MA and Washington, DC offices. Mr. Crane advises clients on structuring complex strategic affiliation arrangements and transactions to comply with the applicable fraud and abuse laws, as well as the variety of other regulatory requirements. His work in defending clients against anti-kickback, Stark Law, false claims, and whistleblower allegations includes litigation, internal investigations, voluntary disclosures, and negotiating settlements and Corporate Integrity Agreements (CIAs). He has appeared before numerous U.S. Attorneys' offices, the FBI, and OIG. In addition, he has served as an expert witness in health care fraud cases. Mr. Crane's practice focuses on Medicare & Medicaid fraud and abuse compliance and reimbursement issues and related laws, including the federal Physician Payments Sunshine Act, meaningful use of EHR technology, under arrangement and provider-based rules, and OIG issues. He has been included in *The Best Lawyers in America* since 2011 for his expertise in health care law. In 2004, Mr. Crane was honored as one of the nation's "Outstanding Fraud and Compliance Lawyers" by *Nightingale's Healthcare News*. Mr. Crane was also named to the Massachusetts *Super Lawyers* Criminal Defense: White Collar list each year from 2004 to 2016 and to *Chambers USA: America's Leading Lawyers for Business* for Massachusetts Healthcare from 2009 to 2012 and 2015–2017. He received his undergraduate degree from Harvard College (1972), a Master's degree in health administration from the University of Michigan (1976), and his law degree from Antioch School of Law in Washington, DC (1983). He is a frequent speaker at AHLA seminars and contributor to various publications. Mr. Crane has served in leadership positions with the American Health Lawyers Association (AHLA), including election as a Fellow (as only the third private-practice fraud and abuse attorney elected), which is one of AHLA's highest recognitions for lifelong leadership.

Gerald "Jud" E. DeLoss (Chapter 19, Behavioral Health) is a Partner at Gozdecki, Del Giudice, Americus, Farkas & Brocato LLP in Chicago, IL, in the firm's Health Care Practice Group. Mr. DeLoss represents health care clients with a particular focus on behavioral health care providers, health information technology (HIT) solution providers, federally qualified health centers (FQHCs), hospitals and research organizations, as well as industry trade and professional associations. Mr. DeLoss has extensive knowledge of HIPAA, HITECH, electronic health records (EHRs), behavioral health privacy, and telehealth requirements. His representation includes compliance and response to breaches. Mr. DeLoss has testified before the United States House of Representatives, Energy and Commerce Committee, as a subject matter expert on 42 C.F.R. Part 2, the federal regulations governing the confidentiality of substance use disorder information. He has also served as an expert witness on health information privacy in court proceedings. Mr. DeLoss guides behavioral health care providers on reimbursement under Medicaid, Medicare, grant funding, private insurance, and managed care. He also counsels providers on strategic acquisitions, along with preparation and negotiation of joint venture and merger agreements. In addition, Mr. DeLoss provides legal representation to address discrimination and exclusion of osteopathic physicians in medical staff privileging and credentialing matters. Mr. DeLoss has written articles and presented on health law issues nationally and internationally, including on health information privacy and security and other compliance matters. He is an active member of the American Health Lawyers Association where he has served as Chair of the Health Information and

Technology Practice Group, Chair of the Behavioral Health Task Force, and currently serves on the Quality Committee to the Board of Directors.

Kyle Y. Faget (Chapter 10, The Relationship between Enforcement and Compliance) is a special counsel and business lawyer with Foley & Lardner LLP. She is a member of the firm's Government & Public Policy Practice and the Health Care, Telemedicine, and Life Sciences Industry Teams. Her practice focuses on advising clients regarding regulatory and compliance matters involving the Food, Drug & Cosmetic Act, the False Claims Act, the Anti-Kickback Statute, the AdvaMed Code, and the PhRMA Code. She has extensive experience in health law, life sciences, and a range of FDA corporate and regulatory areas within the medical device and pharmaceutical industry. Additionally, she has provided clients with strategic and tactical advice regarding government and internal investigations. Her experience includes operationalizing and monitoring compliance with Corporate Integrity Agreements and Deferred Prosecution Agreements and managing Independent Review Organizations. Prior to joining the firm, Ms. Faget held several in-house positions. She has experience in a variety of health care regulatory and compliance matters, including medical affairs, sales, marketing and promotion issues, health care provider grants and charitable donations, and health care professional research grants. She also has extensive experience drafting and negotiating agreements commonly utilized in the life science industry, including health care professional consulting agreements, manufacturing agreements, informed consents, pre-clinical and investigator initiated and sponsor initiated clinical trial agreements.

Emily Black Grey (Chapter 16, EMTALA Compliance) is a partner in the Baton Rouge office of Breazeale, Sachse & Wilson, LLP and is the Section Manager of the firm's health care team, one of the largest in Louisiana. She represents health care providers in a wide range of issues including routine operational matters, regulatory compliance, fraud and abuse, licensing, provider enrollment, contracting, joint ventures, and health care transactions including hospital/physician integration. Ms. Grey's clients range from Fortune 500 companies to individual health care professionals and include hospitals and health systems, surgery centers, pharmacies, physicians and their practices, health care management and consulting companies, and other health care providers. As stated by *Chambers USA*, Ms. Grey's clients praise "her 'positive attitude and orientation towards results and resolution.'" She is noted for her handling of transactional regulatory matters and offers noted experience in licensing. She advises her clients on health care matters such as Stark and anti-kickback laws, EMTALA, state licensing regulations, Conditions of Participation, and other similar requirements. She assists providers who are seeking a new license, revising an existing license or buying or selling a facility. Additionally, she represents providers under scrutiny from licensing and certification agencies including Medicare & Medicaid and before their state licensing boards. She also represents providers in collection suits and in disputes with managed care organizations. Ms. Grey is the Chair of the Hospitals and Health Systems Practice Group of the American Health Lawyers Association, following six years of serving as a Vice Chair of that Practice Group and as the Chair and Vice Chair of the Public Health Systems Affinity Group. She has also held leadership positions with the American Bar Association, the Louisiana State Bar Association's Health Law Section, the Louisiana Law Institute, and the Baton Rouge Bar Association. She is a frequent speaker and author on health care issues for AHLA and for the Louisiana Hospital Association. Ms. Grey graduated from Louisiana State University with a Bachelor's degree in English in 1997, and received her law degree from Louisiana State University's Paul M. Hebert Law School in 2000 where she was a member of the Law Review. She is licensed to practice in Louisiana and Texas.

Gerald M. Griffith (Chapter 23, Exempt Organizations and Other Tax Compliance Issues) is a partner with Jones Day in their Chicago office. He practices in the areas of health care transactions, tax-exempt organizations, and regulatory compliance. He also has served as borrower's counsel on several hospital and long-term care bond issues. Mr. Griffith's transactional practice focuses on significant transactions, with an emphasis on joint ventures and acquisitions. His tax-exempt organizations practice concentrates on defending major IRS audits, obtaining rulings in complex cases, and community benefit matters. Mr. Griffith has represented multiple health systems in major IRS audits. He also is experienced in structuring complex affiliations, including hospital joint operating agreements and other shared control joint ventures. He has obtained several unique private letter rulings from the IRS, including the first ever ruling approving a nonprofit hospital joint operating agreement (PLR 9609012), the first hybrid JOA/merger ruling (PLR 199944046), and the first ruling on disqualified person status of physicians (PLR 201336020). Mr. Griffith also has considerable experience in structuring physician relationships with hospitals, nonprofit governance, executive compensation, academic medical center relationships, voluntary disclosures, and fraud and abuse and Stark Law compliance. He has represented hospital systems, academic medical centers, physician organizations, health maintenance organizations, and colleges and universities. Mr. Griffith is Past President of the American Health Lawyers Association and a member of its Nominating Committee. He is also President of the Illinois Association of Healthcare Attorneys, and he served as chair of the Health Care Law Section of the State Bar of Michigan.

Nancy Bonifant Halstead (Chapter 22, Drugs, Devices, and Life Sciences Entities) is an attorney in the Washington, DC office of Reed Smith. She is a member of the Life Sciences Health Industry Group, practicing in the area of health care regulatory law. Mrs. Halstead works with all types of health industry clients, including acute and post-acute institutional providers, medical device and pharmaceutical manufacturers, independent diagnostic testing facilities, DMEPOS suppliers, laboratories, and hospice programs. Her practice focuses on fraud and abuse compliance (for example, compliance with the federal Anti-Kickback Statute, the Stark Law, and beneficiary inducement prohibition), False Claims Act defense, government

investigations, and Medicare reimbursement. Mrs. Halstead also counsels health care providers and their vendors on health information privacy and security compliance (HIPAA and state law) and digital health issues. Mrs. Halstead graduated from the University of Maryland School of Law with a Health Law Certificate and received a Bachelor of Arts degree in Chemistry from Wake Forest University.

Jake Harper (Chapter 4, Background Checks and Excluded Persons and Chapter 5, Government Program Participation and CMS Billing Revocation Authority) is an associate in the Healthcare Litigation section at Morgan Lewis and focuses his practice on regulatory, reimbursement, and fraud and abuse counseling for a variety of health care providers. He represents health systems, physician practices, hospices, and other industry stakeholders in connection with HHS-OIG exclusion, CMP, and Corporate Integrity Agreements, CMS revocations, terminations, and overpayment appeals. As a former law clerk at HHS-OIG, Mr. Harper has an in-depth knowledge of OIG's exclusion authority as well as the scope and effect of exclusion for both individuals and entities.

Kenneth E. Hooper (Chapter 13, Internal and External Audit Basics) CPA, CFE, CHC is a Director with HBE Advisors LLC. He has over 30 years of experience in public practice including consulting and litigation support services for health care providers. He is a licensed CPA in Idaho, Washington, and Georgia, as well as a Certified Fraud Examiner and Certified in Healthcare Compliance. Mr. Hooper's health care consulting experience includes provider compliance and litigation matters including due diligence, internal investigations, self-reporting and forensic services. Mr. Hooper has testified, been deposed, or consulted on cases in both federal and state courts. He has also served as the interim National Director of Audit and Monitoring for a national third-party billing company and as a chief compliance officer for a health care system while a permanent replacement was recruited.

Gabriel L. Imperato (Chapter 8, What to Do When the Government Knocks and Chapter 9, Managing an Internal Investigation) is the Managing Partner of Nelson Mullins Broad and Cassel's Fort Lauderdale office and is a leader of the Firm's White Collar/Health Care Criminal and Civil Fraud and Compliance Practice. He has practiced health care law in both the public and private sectors for over thirty years and is Board Certified as a specialist in health law by the Florida Bar. He is also Certified in Healthcare Compliance by the Health Care Compliance Association where he sits on the Board of Directors and is a past president of the organization. Mr. Imperato's personal area of practice involves the representation of individuals and organizations accused of criminal and civil health care fraud and handling compliance matters for health care organizations. Prior to joining Broad and Cassel, Mr. Imperato was the Deputy Chief Counsel, Office of the General Counsel, United States Department of Health and Human Services, where he advised and represented various agencies of the Department of Health and Human Services, including the Center for Medicare & Medicaid Services, the Public Health Service, the Social Security Administration and the Office of the Inspector General. Mr. Imperato has extensive criminal and civil trial and appellate experience in administrative, state, and federal courts and has personally handled leading national cases concerning criminal and civil health care fraud and abuse and health care law and policy. He has also handled numerous matters involving the formation of integrated delivery systems and managed care organizations. He is considered a national expert on health care fraud and abuse and compliance and regulatory matters and is a frequent lecturer on these topics. He is a member of the Illinois, Florida, and District of Columbia Bars, the American Health Lawyers Association, the Health Law Section of the Florida Bar, The American Bar Association White Collar Crime Committee and the Subcommittee on Health Care Fraud where he has been the Chairman of the Planning Committee of the American Bar Association's Annual Health Care Fraud Institute since 1995. Mr. Imperato was a long time member of the now-dissolved American Academy of Hospital Attorneys, where he was Chairman of the Reimbursement and Payment Committee and the Health Care Reform Task Force.

Kevin Kifer (Chapter 15, Stark and Anti-Kickback Prohibitions) is an associate attorney in the St. Louis, Missouri office of Husch Blackwell LLP. Mr. Kifer is a member of the firm's Healthcare Regulatory practice and counsels clients in the health care and pharmaceutical research industries on regulatory and transactional matters. Prior to joining Husch Blackwell, Mr. Kifer worked in-house as a Legal Services Fellow for BJC HealthCare in St. Louis, Missouri, where he provided research and analysis on a wide variety of topics, including federal fraud and abuse laws, Medicare reimbursement rules, state and federal employment laws, and medical staff bylaws. Mr. Kifer is a graduate of Rhodes College (BA), University of Missouri-St. Louis (MA), and St. Louis University School of Law (JD, *magna cum laude*). Mr. Kifer is admitted to practice in Missouri and Illinois.

Ronald H. Levine (Chapter 6, Corporate Transparency and Disclosure) is a principal in the Philadelphia office of Post & Schell, PC, heading its national practice in white collar defense, internal investigations and corporate compliance. Mr. Levine conducts internal investigations and assists enterprises and individuals that are subject to government regulation or investigation, criminal and civil. Formerly Chief of the Criminal Division of the U.S. Attorney's Office in Philadelphia, Mr. Levine has extensive experience achieving favorable outcomes for health care systems, pharma and med device manufacturers, and other providers. An elected Fellow of the American College of Trial Lawyers and recipient of the Pennsylvania Association of Criminal Defense Lawyers' Josel Advocacy Award for his work in the U.S. Supreme Court case, *United States v. Elonis* (the "Facebook threats" case), Mr. Levine frequently teaches and speaks on health care law enforcement issues, internal investigations, white collar crime, and trial advocacy. He sits on the boards of the *Business Crimes Bulletin* and PACDL, and he is the former appointed

chair of the U.S. Sentencing Commission Practitioners Advisory Group. Mr. Levine is a graduate of the University of Pennsylvania Wharton School, Oxford University, and Harvard Law School.

Melissa L. Markey (Chapter 18, Health Information Privacy and Security Laws and Chapter 20, Research Compliance) is a shareholder with Hall, Render, Killian, Heath & Lyman, one of the nation's top health law firms, in the Denver, Colorado office, and is licensed to practice as an attorney in Texas, Michigan, Utah, and Colorado. Ms. Markey's practice focuses on cybersecurity, privacy, and life sciences issues, particularly research misconduct and grant compliance, mobile medical applications, and innovations in health technology. She leads the Life Sciences team at Hall Render and has a particular interest in legal issues at the developing edge of technology. Ms. Markey is a Certified Information Systems Security Professional (CISSP), a paramedic, was on the Board of Directors and is now a Fellow of the American Health Lawyers Association, is a member of the Healthcare Information and Management Systems Society (HIMSS), and the computer law sections of the American Bar Association, as well as the State Bars of Texas, Utah, and Michigan. She is a nationally recognized author and presenter on data privacy and security, clinical research, and human subject protection, the clinical-technology interface, research misconduct, and emergency preparedness and response law.

Joseph Metro (Chapter 22, Drugs, Devices, and Life Sciences Entities) is a partner in the Washington DC office of Reed Smith LLP, where he practices within the firm's Life Sciences and Health Industry Group. Mr. Metro's practice focuses on regulatory compliance matters affecting the operations of drug and medical device industry participants, including manufacturers, distributors, providers, and other organizations. He has extensive experience on matters arising under the Anti-Kickback Statute and False Claims Act, as well as government pricing legislation, including the Medicaid rebate program, the 340B drug discount program, the Veterans Health Care Act, and Medicare Part B's "average sales price" payment methodology. Mr. Metro was graduated from Dickinson College in 1986 and from the George Washington University School of Law in 1989.

Macauley Rybar (Chapter 18, Health Information Privacy and Security Laws) is a law clerk for Hall, Render, Killian, Heath & Lyman. He is a third-year JD candidate at the University of Michigan Law School, pursuing health law. Additionally, he holds a Bachelor of Arts from the University of Michigan.

Alexandra "Allie" B. Shalom (Chapter 10, The Relationship between Enforcement and Compliance) is an associate and business lawyer with Foley & Lardner LLP. Ms. Shalom is a member of the firm's Health Care Practice. Her practice focuses on counseling clients in the health care and medical device industries with respect to a wide range of regulatory and compliance matters. Her experience includes advising clients on Medicare & Medicaid reimbursement; internal investigations and audits; self-disclosures; federal and state fraud and abuse compliance; and state licensure issues. She also assists health care clients with a broad range of transactional matters, including mergers and acquisitions and formation of friendly professional corporations. Prior to joining Foley, Ms. Shalom served as a summer associate in the firm's Boston office, where she gained experience in the area of health care. Ms. Shalom's prior experience includes internships with both Health Law Advocates and Beth Israel Deaconess Medical Center's Office of the General Counsel.

Albert W. Shay (Chapter 7, Regulatory Advice and Liability Issues) is a partner in the health care practice of Morgan Lewis & Bockius. His primary area of practice focuses on the representation of hospitals and other health service providers on regulatory, compliance, and payment matters. Mr. Shay frequently advises clients on complex hospital/physician arrangements and their compliance with Stark, Anti-Kickback, Beneficiary Inducement, and other applicable laws. He assists clients in conducting internal investigations of potential compliance issues and works with clients to prepare voluntary disclosures to report and repay identified health care overpayments. Mr. Shay also advises clients in structuring health care business transactions, affiliations, and other contractual relationships, including the acquisition of physician practices and the development of service line management arrangements.

Harry R. Silver (Chapter 11, False Claims) is with the Potomac Law Group in Washington, DC. He received his JD from Columbia Law School, where he was on the editorial board of the *Columbia Law Review.* Mr. Silver served as law clerk to the Hon. Harold R. Medina, U.S. Court of Appeals for the Second Circuit, and subsequently worked for the Appellate Section of the Civil Division of the United States Department of Justice. Since entering private practice in 1979, Mr. Silver's practice has concentrated on defending health care providers in investigations and litigation stemming from allegations of fraud and abuse, representing health care providers before federal and state courts and agencies, in Medicare & Medicaid reimbursement disputes, and advising providers on compliance, reimbursement, and HIPAA issues. Mr. Silver was co-editor of the Third and Fourth Editions of AHLA's *Health Care Compliance Legal Issues Manual*, author of the False Claims Act chapter for all five editions of the Manual, and co-author of the Legal Considerations and Compliance chapter in the Third and Fourth Editions of the Manual. He also authored the Fundamentals of Fraud and Abuse Laws chapter in AHLA's *Deciphering Codes: Fraud & Abuse for Coders and Coding Insight for Healthcare Lawyers*, as well as numerous articles on health care fraud and abuse. He has spoken extensively on health care fraud and abuse issues. Mr. Silver has been a member of AHLA's Quality Council. He is AV® Preeminent™ Peer Review Rated by Martindale Hubbell.

E. John Steren (Chapter 21, Antitrust Laws) is a partner in the Health Care & Life Sciences and Litigation & Business Disputes practices of Epstein Becker & Green, PC, resident in the firm's Washington, DC office. Mr. Steren devotes a significant portion of his practice counseling a variety of health care providers on antitrust matters including civil and government investigations and compliance with Hart-Scott-Rodino Premerger notification requirements. He also focuses his practice on other complex commercial and civil litigation matters. Mr. Steren received a BA degree in economics *summa cum laude* from the University of Maryland, and his JD degree from Georgetown University Law Center. Mr. Steren has written and spoken extensively on antitrust related matters.

Drew Stevens (Chapter 17, Health Care Civil Rights and Nondiscrimination Under Section 1557 of the Affordable Care Act) is an associate at Arnall Golden Gregory LLP in Atlanta, GA and regularly advises health care providers on compliance with the new nondiscrimination requirements under Section 1557 of the Affordable Care Act. He is recognized as an emerging authority on the subject, having written and presented on the topic in multiple publications and conference venues. He is a member of his firm's Hospitals and Health Systems Industry Team and regularly defends providers in connection with litigation and investigations under the False Claims Act. He is a graduate of Emory University School of Law, where he graduated with high honors and received the ABA/BNA Award for Excellence in the Study of Health Law.

Sarah E. Swank (Chapter 16, EMTALA Compliance) is an experienced attorney who has worked as in-house counsel in two national health care systems and as a Shareholder in a nationally recognized law firm. Ms. Swank was Senior Counsel at Dignity Health in Pasadena, California supporting five hospitals, laboratory services, and six CINs and a Shareholder in Ober|Kaler's Health Law Group in the Washington, DC office providing advice and guidance on health care transactions, governance, ACOs, telehealth, compliance, EMTALA, clinical research, IRBs, and health care reform. Before joining Ober|Kaler, Ms. Swank was an Associate General Counsel for Trinity Health in the metro-DC area, where she managed the local legal team and assisted in system-wide initiatives. She started her career as a managed care attorney and government affairs associate in New York State. Ms. Swank works with clients to navigate the complex legal framework facing the health care industry today and to promote access to high quality and safe care by breaking down silos through innovation, technology, clinical research and patient-centeredness.

Teresa A. Williams (Chapter 1, Glossary of Key Terms) is Vice President of Regulatory Services at INTEGRIS Health, Inc. She oversees Legal Services, Corporate Compliance, and Legislative Affairs. She also serves as the system Corporate Compliance and Privacy Officer and Interim General Counsel. She focuses on health care compliance, Medicare & Medicaid reimbursement, provider enrollment, HIPAA privacy, health care contracting, acquisitions, mergers, joint ventures, physician contracting, managed care contracting, clinical research, medical staff issues, tax-exempt issues, policies and procedures, and intellectual property. She is a graduate of Rose State College (AA 1986), the University of Central Oklahoma (BBA, *cum laude*, 1987) and the University of Oklahoma (JD, with distinction, 1991). She is a member of the American Health Lawyers Association, Health Care Compliance Association, and Oklahoma Health Lawyers Association. She is a former member of the Board of Directors of AHLA and currently serves on the Board of Directors of The C.A.R.E. (Child Abuse Response and Evaluation) Center. Ms. Williams is an adjunct professor at the University of Oklahoma College of Law in a Master of Legal Studies Program - Healthcare. Ms. Williams is a frequent author and speaker on health law related topics at local and national seminars for continuing legal and compliance education.

Amanda M. Wilwert (Chapter 14, Medical Necessity, Claims, and Payment Processes) is an associate attorney in the Overland Park, Kansas office of Foulston Siefkin LLP. She is a member of the firm's health care practice group. Ms. Wilwert works with all types of health care clients, including acute and post-acute institutional providers, pharmacies, independent physician groups, and hospice programs. Her major practice areas include health care regulatory matters, HIPAA, HITECH, EMTALA, compliance, patient care issues, consent issues, risk management, and Medicare & Medicaid reimbursement. She frequently represents clients in matters before state licensing boards. She also practices in litigation in the areas of reimbursement and professional malpractice. She is a 2011 graduate of the Washburn University School of Law, where she was an articles editor for the *Washburn Law Journal*. She is a member of the Kansas and Johnson County Bar Associations, the American Health Lawyers Association, the Kansas Association of Hospital Attorneys, and the Kansas Women Attorneys Association.

Howard J. Young (Chapter 4, Background Checks and Excluded Persons and Chapter 5, Government Program Participation and CMS Billing Revocation Authority) is a partner and leader of the Health Care Practice at Morgan Lewis. For over 25 years, Mr. Young has concentrated on health care regulatory, fraud and abuse defense and compliance counseling, and transactions for a wide array of health care organizations. From 1997 to 2002, he was a senior attorney at the HHS Office of Inspector General. He has handled many False Claims Acts, Anti-Kickback Law, exclusion, and other administrative law matters. Mr. Young regularly advises private equity firms and other investors on their transactions involving the health care sector.