

About the Editor

Jennifer R. Breuer, editor of this title and author of Chapter 1, is Vice Chair of Faegre Drinker's Health Care Practice Group and Co-Chair of its Digital Health Team. Ms. Breuer provides strategic counsel to hospitals, health systems, physician practices, other providers, and health technology companies on the transactional, regulatory, and compliance matters they must address in the rapidly evolving health care landscape. She also develops data-sharing and privacy compliance strategies related to the use of electronic health records, health information exchanges, and other technology platforms. Ms. Breuer assists with the formation and operation of telehealth companies and counsels them on regulatory and compliance matters including privacy law, contracting, risk reduction, and breach response. She develops policies, procedures, and compliance programs to ensure compliance with state and federal regulations such as the Medicare and Medicaid Anti-Kickback Statute, Stark Law, HIPAA and 42 C.F.R. Part 2. Ms. Breuer earned a J.D. from Northwestern University Pritzker School of Law and a B.A. from Wesleyan University.

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Kyle Y. Faget, author of Chapter 9, is a partner and business lawyer with Foley & Lardner LLP. She is the Co-Chair of the firm's Health Care Practice Group, Co-Chair, Health Care & Life Sciences Sector—Medical Devices and a core member of the firm's life sciences and telemedicine industry teams. Ms. Faget advises investors, academic medical centers, physician practices, and consultants on a range of business, legal, and regulatory issues affecting the telemedicine industry. She helps companies build and refine corporate compliance programs including advising clients on regulatory and compliance matters involving the Food, Drug and Cosmetic Act, the False Claims Act, the Anti-Kickback Statute, the AdvaMed Code, and the PhRMA Code. She regularly drafts and negotiates agreements required for the development and commercialization of pharmaceutical and medical device products, including licensing agreements, collaboration agreements, clinical trial agreements, and an array of services agreements. Prior to joining the firm, Ms. Faget held in-house positions at pre-commercial and commercial stage companies. She earned a J.D. from the University of Michigan Law School, a certificate in post-baccalaureate pre-medical studies from Bryn Mawr College, and an A.B. in physiological psychology, with a minor in neuroscience, from Smith College.

Andrea L. Frey, co-author of Chapter 2, is an associate at Hooper, Lundy & Bookman as well as Co-Chair of the firm's Digital Health Practice Group and Reproductive Health Practice Group. She regularly counsels health care providers and suppliers on a wide range of transactions and regulatory matters, with a particular expertise in digital health. Ms. Frey's experience includes assisting clients navigate the complex web of state and federal health privacy laws, state-level scope of practice issues (e.g., licensure, informed consent, practitioner-patient relationship establishment), corporate practice of medicine, and remote prescribing. Throughout the COVID-19 pandemic, she has also helped clients parse through the rapidly evolving federal and state developments and regulatory changes, particularly with regard to the provision of telehealth services, and frequently counsels clients on the development and operation of nation-wide digital health care platforms and other business lines. Ms. Frey earned her undergraduate degree from Tufts University and her law degree and master of public health from the University of Washington.

Jennifer A. Hansen, co-author of Chapter 2, is an equity partner at Hooper, Lundy & Bookman and the Co-Chair of the firm's Medical Staff Practice Group. She advises on telehealth credentialing issues and represents health care providers in a wide range of litigation. A significant portion of Ms. Hansen's practice involves advising medical staffs in credentialing and privileging matters, governance, by-laws, policies and procedures, rules and regulations, investigations, and reporting to the state professional licensing boards and the National Practitioner Data Bank. Her representation of health care providers also includes payor/provider disputes and post-acute care facility defense. Ms. Hansen earned her undergraduate degree from the University of Wisconsin-Madison and her law degree from the University of Minnesota Law School.

Elinor A. Hiller, co-author of Chapter 5, is a partner in Alston & Bird's Health Care Policy practice. Along with Sean Sullivan, she co-leads the firm's Digital Transformation of Health Care initiative. Ms. Hiller represents clients across the health care industry on legislative and regulatory policy matters, with a focus on Medicare Advantage and Part D, Medicare fee-for-service payment rules, interoperability and price transparency, and federal insurance oversight. She previously served at the Centers for Medicare and Medicaid Services (CMS) and was an advisor to the CMS Administrator on issues including Medicare, telehealth, and price transparency. Earlier in her time at CMS, Ms. Hiller was the director of the Medicare Parts C and D Analysis Group in the Office of Legislation, where she managed interactions between the agency and Capitol Hill on a portfolio of issues including provider integrity. Ms. Hiller is a graduate of Georgetown University Law Center and Wellesley College.

Melania Jankowski, co-author of Chapter 3, is an associate in the business department of Hooper, Lundy & Bookman. She assists health care providers and suppliers on issues involving transactions, regulatory compliance, and innovative business arrangements. Ms. Jankowski focuses largely on working with national telehealth platforms and digital help startups, helping them navigate various state-level scope of practice, licensure, and corporate structuring considerations. Previously, she worked as an associate for a national law firm, advising primarily on regulatory issues facing health care providers. Ms. Jankowski also served as a law clerk for the Federation of State Medical Boards (FSMB), where she gained invaluable experience tracking medical licensure and telehealth waivers during the COVID-19 pandemic. She earned a J.D. from Boston College Law School and a B.A. from the University of Southern Maine.

Amy M. Joseph, co-author of Chapter 6, is a partner in the Boston office of Hooper, Lundy & Bookman, P.C. She advises a wide variety of health care providers on business and regulatory matters, including for-profit and nonprofit health systems, health care information technology companies, management organizations, and physician groups. A significant portion of Ms. Joseph's practice is focused on fraud and abuse compliance, including counseling and advice regarding compliance of potential business structures with federal and state anti-kickback and self-referral laws, health

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Amy F. Lerman, author of Chapter 4, is a Member of the Health Care and Life Sciences Practice at Epstein Becker & Green, P.C. (EBG). Ms. Lerman's diverse practice includes supporting clients on matters involving government investigations, audits, and related claims of fraud, false claims, and other noncompliant behaviors as well as a broad scope of regulatory questions, advising on compliance-related questions, and the development of corporate compliance program infrastructures. She also supports EBG's telehealth clients through their "life cycle" of legal needs and helps these clients develop and execute strategies for company structure, development, and growth, while also advising on trends and the development of regulatory strategies for growing and expanding telehealth businesses to achieve nationwide footprints. Ms. Lerman earned her Masters in Public Health from Columbia University and her J.D. from the University of Maryland. She is the lead author of EBG's Telemental Health Laws app, a comprehensive survey of state telehealth laws, regulations, and policies for mental and behavioral health practitioners and stakeholders across all 50 states, the District of Columbia, and Puerto Rico. Ms. Lerman also has guest lectured on digital health law at Cornell Tech since 2018.

Joseph P. ("Joe") McMenamin, author of Chapter 8, is a physician-attorney and a partner with Christian & Barton, LLP in Richmond, Virginia concentrating on the law of digital health. Mr. McMenamin advises institutional and professional telehealth service providers, academic medical centers, remote monitoring services, trade associations, telehealth platform companies, private equity firms, and telecoms on a broad array of medico-legal questions arising from distance care and, more recently, on the application of augmented intelligence to health care in general and to telemedicine in particular. He writes and lectures extensively on these and related topics. Mr. McMenamin also serves as general counsel to the Virginia Telehealth Network and is a member of the Legal Resource Team of CTeL, the Center for Telemedicine and eHealth Law. He graduated *summa cum laude* from Washington and Lee with a B.S. in chemistry and holds medical and law degrees from the University of Pennsylvania.

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Melissa Sobel Snyder, author of Chapter 7, is an associate in the Philadelphia office of Duane Morris LLP, where she practices in the firm's Health Law Practice Group. Ms. Snyder focuses her practice on health care regulatory compliance and health information technology matters. She advises clients, including hospitals, outpatient providers, long-term care facilities, physicians, and other health care providers on a variety of legal issues, including HIPAA and state privacy laws, federal and state licensing and certification, telemedicine matters, and across-the-board regulatory compliance. Ms. Snyder also regularly assists subcontractors and vendors providing services to the health care industry and companies providing health information technology with HIPAA and health care data privacy issues. In addition, she also has experience assisting health care providers undergoing changes of ownership and control with regulatory and licensure issues associated with those transactions. Ms. Snyder received her B.A., *magna cum laude*, from Tufts University, and her J.D., *cum laude*, from the University of Pennsylvania Law School. She also earned a Master of Bioethics from the University of Pennsylvania School of Medicine.

Sean T. Sullivan, co-author of Chapter 5, is a partner with Alston & Bird's Health Care Group and co-leads the firm's Digital Transformation of Health Care team with Elinor Hiller. Mr. Sullivan assists health care providers and business associates, including health care technology companies, in avoiding liability by ensuring regulatory compliance in operations; advising on business forms and transaction structures; investigating, disclosing, and resolving potential noncompliance; and providing regulatory support to litigation and transactions as necessary. He also regularly advises

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private equity and other investors on the regulatory risks and structuring considerations associated with investing in the health care industry. Mr. Sullivan started his legal career in the U.S. Army JAG Corps, where he advised commanders on regulatory matters and defended soldiers and officers accused of misconduct in courts martial and hearings. Since leaving active duty, Mr. Sullivan has focused his career on advising national health care providers in regulatory actions, policy review, compliance, reimbursement, and liability prevention, including corporate practice of medicine, HIPAA, Stark Law, Anti-Kickback Statute, False Claims Act, and CMS rules. Mr. Sullivan earned his J.D., *cum laude*, from Georgia State University College of Law and his B.A. from Emory University.

Christine Burke Worthen, co-author of Chapter 3, is a partner with Nelson Mullins Riley & Scarborough LLP. She provides legal and strategic advice to hospitals, health systems, physician practices, and behavioral health providers as well as post-acute care and other ancillary providers. Ms. Worthen has broad experience working on matters pertaining to Medicare reimbursement, participation in CMS Innovation Center payment models, managed care contract negotiations, and value-based payment arrangements with insurance companies, self-insured employers, and Medicare Advantage plans. She also provides counsel on the regulatory, operational, and financial considerations necessary to navigate the evolving payment landscape, to secure sustainable fee for service agreements and to navigate the various components of risk, ranging from pay for quality, to shared risk, and ultimately to full risk.

Ms. Worthen also addresses privacy and security issues under HIPAA and the Part 2 regulations that may arise when integrating, using, and sharing claims and clinical data. She advises on other areas of concern for providers such as payer policies and price transparency as well as the reimbursement, licensing, and other regulatory issues involved in deploying telehealth as a strategy for population health arrangements. She also represents providers in payment disputes under their commercial contracts. Ms. Worthen earned a J.D. from New England Law—Boston, an LL.M. in Taxation from Boston University School of Law, and a B.A., *cum laude*, English Honors and French Language and Literature from Boston University.