HLB HOOPER LUNDY BOOKMAN

CAPABILITIES

DIGITAL HEALTH

Advancements in health care have often been products of scientific and technological innovation. Today, the pace, complexity, and scope of developments in digital health provide opportunities and risks in equal measure for health care providers and the companies that develop these products and services. Hooper, Lundy & Bookman practices at the intersection of health care, technology, policy, and the law, helping our clients leverage innovation to improve patient care, achieve business objectives, and move health care forward.

HLB's nationwide digital health practice is anchored by attorneys who have spent their careers at the vanguard of health care innovation, not only as counsel, but also as industry participants. We understand the compliance and regulatory issues implicated by marketing and integrating new technologies into the business and practice of medicine. Our government relations and public policy practice complements this with professionals who have the pulse of legislators and federal policymakers who seek to regulate these technologies. Our team has the ability to provide helpful outlook and in the sector. Many of HLB's attorneys and government relations professionals are recognized subject matter experts in digital health law and policy.

We frequently counsel health care providers and suppliers – including hospital systems, provider organizations, health information organizations and exchanges (HIOs and HIEs), national telehealth platforms, developers, investors, and digital health start-ups – on matters related to regulatory compliance, transactions, and innovative business arrangements.

Maximizing the Value of Digital Health for Health Care Providers

HLB works with health care providers of all types to help them maximize patient care and business benefits and minimize the compliance risks involved with licensing, purchasing, deploying and developing digital health solutions.

Our broad range of digital health representation for providers includes:

- Develop and refine new business arrangements for technology-enabled health care services, such as remote radiology programs or electronic ICUs
- Negotiating and drafting technology and outsourcing agreements
- Analyzing interoperability and information blocking requirements
- Determining data exchange requirements, such as under Trusted Exchange Framework and Common Agreement (TEFCA), California's Health and Human Services Data Exchange Framework, and Data Use and Reciprocal Support Agreements (DURSA)
- Structuring electronic medical record exchanges and joint ventures between providers
- Drafting, negotiating, and analyzing data usage licensing agreements
- Assisting with IT systems and hardware procurement
- Assisting with the implementation of open-source systems
- Drafting, negotiating, and analyzing software and SaaS license agreements
- Developing and reviewing information privacy and security compliance programs
- Applying fraud and abuse compliance programs to the deployment of digital health technologies
- Drafting, negotiating, and analyzing clinical trial and co-development agreements between providers and digital health companies
- Providing strategy, counsel and government relations service in digital health policymaking

Helping Digital Health Companies Innovate, Scale, and Thrive

HLB helps both established and early-stage digital health companies navigate a complex and constantly evolving business, policy and regulatory landscape. Our decades of experience working with those at the cutting-edge of health care has provided us with an intuitive understanding of the short and long-term issues they face. Just as speed and accuracy are the defining characteristics of many new technologies, HLB's expansive, multidisciplinary capabilities and our established presence in key innovation hubs allow us to deliver cost-efficient, consistent, and comprehensive counsel on the full range of transactional, operational, and regulatory issues facing digital health companies.

Our digital health lawyers draft and negotiate health care technology agreements of all kinds, including those involving SaaS solutions, data sharing agreements, software licenses, business associate agreements, HIO/HIE licensing, participation and data sharing agreements and policies. Our compliance counseling on issues, from data protection and patient privacy to the corporate practice of medicine to fraud and abuse investigations, helps digital health companies avoid costly and disruptive missteps that could threaten their business.

In transactional matters, we structure arrangements between technology and health care providers that address corporate practice, fraud and abuse, and other health care licensing compliance requirements. HLB provides counsel on mergers, acquisitions, strategic partnerships, outsourcing agreements, and corporate governance matters that help our clients achieve their business objectives and facilitate continuing innovation in health care delivery.

HLB has substantial experience structuring, operationalizing, and scaling "friendly PC" arrangements across jurisdictions and helping our clients build businesses that comply with state-level corporate practice of medicine restrictions so they can seamlessly expand across state lines. We also assist venture capital and private equity firms in making significant investments in digital health.

At the Forefront of Telehealth

Few firms offer HLB's depth and breadth of telehealth experience, from synchronous to asynchronous telehealth solutions, remote patient monitoring, mobile health, and deploying artificial intelligence in health care. We have been on the front lines of telehealth's legal, technical, and business evolution for decades, with clients ranging from stealth start-ups to established 50-state telehealth platforms and hospitals and health systems.

The cross-jurisdictional nature of telehealth and its intersection with multiple regulatory and licensing regimes requires the ability to assess and address unique compliance issues wherever our clients' tools are used to serve patients. HLB's attorneys, practicing from coast to coast, can quickly and clearly supply the guidance needed to facilitate compliant practices and transactions for telehealth suppliers and providers. Additional legal and compliance issues that HLB regularly advises clients related specifically to the delivery of health care services via telehealth include:

- Telehealth practitioner licensure requirements and scope of practice issues
- Credentialing and privileging of telehealth providers
- Privacy, security, and confidentiality considerations in the use of telehealth
- Coverage and reimbursement for telehealth services by federal health care programs, commercial payors, or on a cash-pay basis
- Remote prescribing of legend and controlled medications
- Federal and state self-referral and kickback laws
- Liability risk management

Navigating Artificial Intelligence (AI)

For more than 35 years, HLB has guided our health care clients through waves of technological change and the evolving legal and regulatory frameworks and novel issues that inevitably follow in their wake. We leverage that industry-leading experience to help stakeholders navigate the challenges that come with the rapid rise and expanding role of AI in the health care industry.

Although AI has been used in certain corners of health care for years, the exponential advancement of AI technology has spurred an equally rapid increase in investment in and reliance upon AI systems throughout the industry. Given AI's power to deliver advancements in care delivery, administrative tasks and create new touchpoints for patient engagement, the rush to

harness AI is hardly surprising.

HLB has the experience, resources, and knowledge needed to help our clients develop strategies and best practices that minimize risks associated with AI while allowing them to reap its benefits. Our attorneys have stood at the forefront of technological change in the health care industry for decades, understanding the mechanics of new innovations and developing strategies to address their legal, practical, and financial implications.

Our AI-related capabilities are built on a foundation of both industry expertise and the insights of the attorneys in our robust, nationwide digital health and technology practice. The well-earned credibility and network of productive relationships of HLB's government relations and public policy professionals in Washington, D.C. facilitate our ability to impact the direction and evolution of AI policy in a way that advances the interests of both providers and patients and strikes the right balance between fostering innovation and establishing guardrails for consumer protection.

The counsel we provide encompasses all health care regulatory issues implicated by the adoption and use of artificial intelligence in health care delivery, including:

- Data privacy and security
- Unlicensed practice of medicine
- Corporate governance
- Informed consent
- Billing compliance
- Anti-kickback laws
- Bias and unlawful discrimination

Government Relations and Public Policy Services

With an ever-innovating digital health landscape, it is critical for providers, vendors, and developers to keep up to date, as well as be a part of the legislative and regulatory process as policymakers regulate different aspect of these technologies. Our government relations professionals work with clients to monitor and analyze the political outlook to know what is coming and strategize how best to provide expertise and advocate. We have worked with clients as they navigate telehealth, remote patient monitoring, AI, interoperability, and cybersecurity and data privacy, among other areas. HLB's bipartisan policy and lobbying professionals provide comprehensive services to build relationship in Congress and federal agencies and ensure a seat at the table as policy is being drafted and negotiated in this fast-paced environment.

Representative Digital Health Experience

The range of our digital health experience includes:

- Navigating corporate practice of medicine ("CPOM") laws to structure and establish hundreds of PC-MSO relationships, and scaling many across all 50 states
- Analyzing sponsorship and other promotional collaborations among providers and digital health companies under fraud and abuse law
- Negotiating intellectual property rights among digital health clinical trial participants
- Providing (and continuously updating) health systems and digital health companies with 50-state surveys on scope of practice issues including licensure, prescribing, patient consent, telehealth-specific registration, and non-physician practitioner supervision requirements
- Representing digital health companies (both buyer and seller) in significant mergers, acquisitions, and strategic affiliations
- Performing regulatory diligence for venture capital and private equity investors on $100m+ investments in innovative digital health platforms
- Assisting leading academic medical centers ("AMCs") and other health system clients developing comprehensive telehealth policies and procedures (including to address proxy credentialing) and multi-state practice structures to deliver services nationally via telehealth, including remote patient monitoring
- Helping scaling digital health companies develop practical yet comprehensive regulatory compliance programs
- Providing regulatory counsel ahead of material funding events from pre-seed rounds to pre-IPO
- Counseling clients on the myriad regulatory compliance, privacy, fraud and abuse (kickback and self-referral), and contracting issues which arise in the lifecycle of a digital health company

– Navigating clients through the complexities of controlled substances prescribing involving the interplay between the Controlled Substances Act (as amended by the Ryan Haight Act) and state law
– Assisting health systems and digital health companies with evolving reimbursement landscapes, including Medicare, Medicaid, and private payor reimbursement.

RELATED SERVICES

Academic Medical Centers and Teaching Hospitals

Business Transactions

Compliance

Fraud and Abuse, Stark, Anti-Kickback Counseling and Defense

Government Investigations

Health Information Privacy and Security

Hospitals and Health Systems

Medicare, Medicaid, Other Governmental Reimbursement and Payment

Mergers and Acquisitions

Pharmacies

Physicians, Medical Groups, Medical Foundations, and Independent Practice Associations (IPAs)

Skilled Nursing Facilities (SNFs) and Long-Term Care Providers

KEY CONTACTS



Andrea Frey
Partner
San Francisco, San Diego



Stephen K. Phillips
Partner
San Francisco



Eric M. Fish
Partner
Washington, D.C.



Paul Deeringer
Partner
San Francisco



Monica Massaro
Principal, Government Relations & Public Policy
Washington, D.C.



Claire Ernst
Director, Government Relations & Public Policy
Washington, D.C.



Alex M. Brill
Economic Policy Advisor



Caitlin Callahan
Associate

Ross E. Campbell
Of Counsel



Kelly A. Carroll
Partner



Sven C. Collins
Partner



Martha P. Cramer
Associate



Paul Deeringer
Partner



Kelly Lavin Delmore
Chair, Government Relations & Public Policy



Claire Ernst
Director, Government Relations & Public Policy



Eric M. Fish
Partner



Andrea Frey
Partner



David A. Hatch
Partner



Andrew Hayes
Associate



Cole M. Hoyt
Associate



Kimia S. Khatibi
Associate



Monica Massaro
Principal, Government Relations & Public Policy



Sunaya Padmanabhan
Associate



Katrina A. Pagonis
Partner



Stephen K. Phillips
Partner



Kerry K. Sakimoto
Associate



Erin R. Sclar
Associate



Michael Shimada
Associate



David J. Vernon
Partner