

# Digital Health and Other Health Technologies

Advancements in health care have often been products of scientific and technological innovation. Today, the pace, complexity, and scope of developments in digital health and health information technology (HIT) provide opportunities and risks in equal measure for providers and the companies that develop these products and services. Hooper, Lundy & Bookman practices at the intersection of health care, technology, 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 and technology 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 marketplace challenges and economic imperatives involved in bringing new products to market, as well as the ever-changing compliance and regulatory issues implicated by integrating those products into the business and practice of medicine.

As thought leaders in digital health law, telemedicine, and health information technology, HLB counsels health care providers and suppliers, including hospital systems, provider organizations, national telehealth platforms, investors, and digital health start-ups on issues involving regulatory compliance, transactions, and innovative business arrangements.

## **Helping Health Care Technology Companies Innovate, Scale, and Thrive**

HLB helps both established and early-stage technology companies navigate a complex and constantly evolving business 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 stakeholders.

HLB drafts and negotiates health care technology agreements of all kinds, including those involving SaaS products, data sharing agreements, software licenses, business associate agreements, HIE licensing, and participation and data sharing agreements and policies. Our compliance counseling on every issue, from data protection and patient privacy to the corporate practice of medicine to fraud and abuse investigations, helps technology companies avoid costly and disruptive missteps that could pose existential threats to their work.

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 PC-MSO 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 and health care technology ventures.

## **At the Forefront of Digital Health and Telemedicine**

Few firms offer HLB's depth and breadth of digital health 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 digital health's legal, technical, and business evolution for decades, with clients ranging from stealth start-ups to established 50-state telehealth platforms.

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.

Our attorneys' digital health and telemedicine 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
- 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 telehealth's evolving reimbursement landscape including Medicare, Medicaid, and private payor reimbursement

### **Maximizing the Value of Health Information Technology for Providers**

HLB works with providers of all types – national hospital chains, physician groups, long-term care facilities, pharmacies, health information organizations (HIOs) and others – to help them maximize patient care and business benefits and minimize the compliance risks involved with evolving health information technology.

Our broad range of HIT representation for providers includes:

- Electronic medical record exchanges and joint ventures between hospitals and physician groups
- Data exchanges, such as TEFCA, California's Health and Human Services Data Exchange Framework, and Data Use and Reciprocal Support Agreements (DURSA)
- Technology and outsourcing agreements
- Interoperability and information blocking
- Drafting, negotiation, and review of data usage licensing agreements
- IT systems and procurement
- Implementation of open-source systems
- Drafting, negotiation, and review of software purchase and license agreements
- Information privacy and security compliance program development and review