

## Health IT

# Practical business & regulatory solutions for the digital health industry



### Whether you are seeking to

- implement an electronic health record, telemedicine, or mobile health system
- navigate regulatory and compliance issues governing Health IT
- address HIPAA privacy and security, patient privacy, or cyber-attacks
- assess vendors and potential partners for security and legal compliance

our team understands the digital health environment and can guide you step by step.

### We work with clients to manage

- Dynamic, complex, and technical agreements for the implementation of HIT and digital health products and services
- Use of emerging technologies, ranging from the Internet of Things (IoT) to Artificial Intelligence (AI) to Blockchain
- Data privacy and security issues related to telemedicine, mHealth, telemedicine, and other digital health verticals
- Regulatory and compliance risks and issues
- Policies and processes to comply with or avoid HIPAA regulations and protect IT assets
- Meaningful Use/MACRA requirements
- A mobile and ever-changing workforce

### Interdisciplinary team with diverse experience and perspectives

- Attorneys with prior experience as chief privacy officers, information technology professionals and government enforcement regulatory roles
- Enterprise-wide counsel for customers and vendors developing, buying and selling HIT, digital health, mHealth and telemedicine services and products

### Related Practice Areas

[Blockchain & Digital Currency](#)

[Cybersecurity & Data Breach Response](#)

[Cybersecurity & Data Privacy](#)

[E-Discovery - Encompass](#)

[E-Discovery & Information Governance](#)

[Emerging Growth & Venture Capital](#)

[Healthcare](#)

[Mergers & Acquisitions](#)

[Privacy & Data Management](#)

[Private Equity](#)

[Records & Information Governance](#)

[Technology](#)

### Related Industries

[Health Insurance](#)

[Healthcare](#)

[Technology](#)

- Compliance and regulatory teams across multiple industries, with team members that include attorneys practicing in intellectual property, cybersecurity, corporate, regulatory, healthcare, and technology law
- Counsel to academic medical centers, integrated health systems, and community hospitals and practices on strategic and technology acquisitions, initiatives and transactions

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### Our clients span the healthcare and digital health industries

- Biotechnology and pharmaceutical companies
- Business associates
- For-profit and not-for-profit health systems, hospitals, physician practices, and dental providers
- Healthcare data analytics firms
- HIT and digital health product and service providers
- Medical device companies
- Medical software vendors and developers
- Practice management companies, MSOs, and DSOs
- Telehealth, mobile health, and telemedicine companies

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### Creative, value based solutions for enduring results

HIT is not one thing . . . it's many things. That's why we can engage all of our clients' needs, whether involving machine learning, big data, distributed ledgers, FHIR, a learning health system or simply negotiating a business associate agreement. Our interdisciplinary team matches cutting-edge knowledge with practical experience to address today's crisis (ransomware, audit) and plan for the next generation (funding, IT acquisition).

### Our HIT and digital health services allow you to

- **Acquire, sell, merge, and finance IT companies** within the healthcare technology sector or partnering with providers
- **Assess risks** in connection with ongoing operations, acquisitions, and new service offerings and technology platforms
- **Complete transactions** by setting information lifecycle governance systems
- **Design technology structures,** policies, and practices
- **Develop and implement vendor assessment, data security, and compliance programs** internally and on behalf of clients' customers
- **Develop and protect new innovations, processes, and products** that solve market needs
- **Implement outsourcing, licensing, and development agreements,** including business process and information technology outsourcing

- **Plan and start up digital health IT companies** through our experience with independent and institutional healthcare investors
- **Stay compliant** with evolving healthcare laws and regulations, including HIPAA, FCC, and state rules and protect the privacy and security of personal health information including business associate requirements
- **Structure products and partnerships** to provide long-term solutions to increase and improve the treatment of patients
- **Train and educate employees** on best practices in the areas of EHR, patient privacy, data security, and data breach reporting
- **Use mobile devices to transmit and access electronic patient records**, including physician use of mobile devices

## Why Nelson Mullins?

- Practical business mindset
- Experience across a wide spectrum of industries and business models
- Multi-disciplinary team
- Predictability and cost efficiency
- Industry experience with vendors, servicers, healthcare IT financing sources, privacy and security consultants, and governmental relationships close to policy makers in emerging fields

## Experience

Following is a selected sampling of matters and is provided for informational purposes only. Past success does not indicate the likelihood of success in any future matter.

- Represented clients in development of regional and enterprise-wide health information exchange organizations, including establishment of governance structures, data use agreements, privacy and security policies and procedures, and advice on operational matters
- Represented hospitals, physicians, and business associates in responding to data breaches and Office for Civil Rights investigations
- Assisted multi-hospital system in responding to post-payment Meaningful Use Stage 1 audits and in preparing for compliance with Meaningful Use Stage 2 requirements
- Counseled variety of provider clients and business associates on whether specific data breach circumstances require breach notification under HIPAA and applicable state data breach laws, identified mitigation strategies, and assisted with reporting obligations
- Assisted hospital systems in addressing "one patient, one record" safeguards to implement when moving to single electronic health record system to be used by all provider entities within the systems

- Assisted hospitals and physician practices in implementing electronic health record systems, including preparing privacy and security policies, crafting patient portal and remote access agreements, and preparing contracts for the donation of electronic health record technology items and services in accordance with Stark law and Anti-Kickback Statute requirements
- Prepared HIPAA/HITECH policies and procedures for hospital systems' self-insured health plans
- Reviewed and negotiated health information technology agreements, including electronic health record software contracts, cloud storage agreements, value-added reseller agreements, and clinical data registry agreements
- Counseled healthcare analytics start-up on regulatory implications of licensing de-identified health data from organizations and sub-licensing such de-identified data sets to organizations seeking large data sets
- Represented telemedicine start-up in assessing possible corporate structures and understanding resulting fraud and abuse, corporate practice of medicine, reimbursement, data privacy, data security, and operational limitations and requirements
- Prepared terms of use, data protection, privacy and ownership guidelines, HIPAA/HITECH/FTC compliance safeguards, liability limitations and trade secret protection for newly-created mobile application used as a complex care management solution
- Counseled healthcare providers and technology vendors on health information privacy and security obligations under HIPAA and HITECH, including responses to HIPAA breaches and audit inquiries
- Advised hospital systems on healthcare IT matters and participation in Health Information Exchange (HIE) and data sharing networks
- Represented Health Information Exchange in preparing documentation and contracting provisions for use with participants
- Represented hospital systems and healthcare providers in creation of HIPAA privacy programs
- Represented hospital system in the acquisition of Electronic Medical Records (EMR) software system
- Represented Health IT company as outside general counsel in extended care space
- Represented pathology laboratory in drafting and negotiating EMR donation software agreements
- Represented hospital systems and healthcare providers in addressing IT and data management agreements and strategies
- Represented pharmacy company in medical/pharmacy software and claims management
- Assisted clients in roll-outs of web-based application implementing personal health record, clinician collaboration, and related tools and functionality
- Negotiated numerous multi-million dollar service agreements relating to SaaS services, data ingestion, data aggregation, secure texting, cloud hosting, and numerous other services
- Negotiated agreements for data analytics, computer learning, and similar services