

Health Information Technology

The Obama administration has set an ambitious goal of full adoption of electronic health records (EHRs) by 2014, and the Health Information Technology for Economic and Clinical Health (HITECH) Act has established financial incentives for hospitals and physicians participating in the Medicare or Medicaid programs who engage in “meaningful use” of EHRs. In addition, the Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), Federal Communications Commission (FCC), and other government agencies have indicated plans to reform regulations within their respective jurisdictions that could directly or indirectly affect health IT, potentially changing how new technologies come to market, how companies comply with industry regulations, and how these agencies interact. To ensure that our clients do not miss a beat, Mintz Levin and ML Strategies, our government relations affiliate, continually monitor relevant legislative and administrative developments and maintain relationships with decision makers in Congress and at key government agencies.

Of course, developing, marketing, and implementing health IT can be very complex. Technology licensing and other business arrangements must comply with state and federal privacy and security rules, health care fraud and abuse regulations, and, for wireless devices, FCC and FDA requirements. Mintz Levin brings together attorneys across various disciplines to advise clients effectively on all facets of health IT transactions.

Because we work with both vendors and end-users, Mintz Levin has the ability to view every transaction from multiple perspectives and to successfully guide clients through the range of issues that emerge. For example, we counsel software and technology companies that are developing and marketing health IT, yet we also work extensively with health care providers and third party payors seeking to integrate legacy systems and to implement new capabilities.

As always, new opportunities raise new questions. Mintz Levin attorneys have the background and experience necessary to help you address them.



Representative Engagements

- Representing several clients in the negotiation of agreements for the outsourcing of services to vendors in India, including services for the processing of healthcare data and financial data
- Advising a vendor of clinical information systems for use in critical care settings (such as Operating Rooms (ORs) and Intensive Care Units (ICUs))
- Assisting with the negotiation of license and services agreements with hospitals and health systems, both private and governmental, around the world, including throughout Europe, Australia and Canada
- Representing a vendor of web-based telehealth solutions used for the delivery of online care. Negotiation of license and services agreements with health plans and health care delivery systems in Australia, Argentina and elsewhere
- Counseling on the negotiation of a broad range of distribution and reseller agreements for health IT companies around the world, including in China, Japan, Sweden, Germany, Denmark, Australia, and the UK
- Representing Humedica, Inc. in its sale to UnitedHealth Group including:
 - structure of various complex data acquisitions and transfers supporting the primary functions of its business - data aggregation, quality analysis, benchmarking and research
 - compliance with evolving federal and state privacy and security requirements and the interplay between them
 - strategic advice for simplifying transactions administratively while maximizing the utility of data for Humedica's customers

Service Offerings



Getting Products to Market

We advise clients – both end-users and vendors – on commercial licensing transactions, distribution arrangements, and strategic collaborations. We regularly structure and negotiate domestic and international agreements governing joint technology development, licensing and distribution, hardware and systems acquisition, outsourcing, and other complex transactions.



HITECH Funding and Meaningful Use

The HITECH Act provides \$36 billion to promote the implementation of health IT, especially the adoption and meaningful use of EHRs. To ensure that clients receive timely, effective advice on the qualifications for receiving federal incentives for EHR adoption, we constantly monitor regulatory developments in this area. Further, we are already advising clients on the funding that will be available, the qualifications for obtaining it, and the application process.



Stark and Anti-Kickback Compliance

Because health IT transactions can create financial and business relationships among health care providers, payors, and vendors, the parties must consider how to avoid running afoul of state and federal health care fraud and abuse laws. Our health law attorneys are well-versed in the requirements of the safe harbor to the Anti-Kickback Statute and the exception to the Stark Law governing donations of EHR systems and e-prescribing technologies and can advise clients on how to structure EHR donation arrangements to avoid health care compliance pitfalls.



Privacy and Security/Data Breach Counseling

Mintz Levin attorneys have substantial knowledge of the HIPAA Privacy and Security Rules, and we are tracking and analyzing new requirements enacted as part of the HITECH Act. We also advise clients on state-mandated privacy protections, data security and consumer protection laws, as well as privacy and personal data protections under European Union and international law. Our work also includes conducting information privacy and security audits, assisting clients with the development and implementation of comprehensive privacy and security compliance programs, advising on compliance with subpoenas and third-party requests for information, and counseling clients on the investigation, mitigation, and resolution of data breaches. We have also successfully defended clients in both civil and criminal privacy law enforcement actions.



Emerging Technologies

While the FDA governs the approval, manufacturing, and promotion of new health care devices, the FCC makes spectrum available for their operations and regulates the cellular and other wireless carrier networks over which they operate. In addition, the American Recovery and Reinvestment Act provides for additional funding to develop broadband infrastructure to support telemedicine programs and rural health initiatives. We combine our communications law practice with our health law and FDA experience to advise clients on the cutting-edge issues facing companies in the emerging technology space.

Representative Engagements (contd.)

- Providing strategic and legal advice to the Massachusetts Health Information Technology Council, which is charged with development of a statewide Health Information Exchange
- Representing hospital systems in strategic collaborations with major IT companies
- Assisting integrated health care providers seeking to revamp and integrate their IT systems for revenue cycle management, billing, and patient administration
- Negotiating strategic collaborations with consumer health portals, e-prescribing vendors, payment processing service providers, and consumer health content publishers for an innovative provider of online care
- Acting as general counsel to an international software company providing clinical information and EHR systems for critical, peri-operative, and acute care environments
- Advising the independent state agency formed to manage Massachusetts's health insurance program on the large-scale outsourcing of its customer service center operations
- Serving as general counsel to a software company providing an automated platform for case, disease, and population management
- Advising a multispecialty physician group on the procurement of an EHR system

Connect

888.908.1933 • www.mintz.com