



Duane Morris healthcare clients continue to witness the increasing influence and complexity of information technology in the delivery of healthcare. The delivery of healthcare wirelessly impacts reimbursement, privacy, practice of medicine and regulatory legal issues, among others. The use of application software (apps) on a portable phone or tablet or web-based software accessed through a traditional medical device fall under the new area of “mobile health” (mHealth). Other terms that are used to describe this new phenomenon include “telemedicine,” “digital health” and “health information technology” (HIT). Virtually any entity or individual who participates in the healthcare system is affected—healthcare providers such as hospitals, physicians and nursing homes; health plans and payors, including Medicare and Medicaid; and provider and plan vendors, such as entities that perform patient data analysis, support the development of health information exchanges/organizations (HIEs or HIOs) or provide data storage. Entrepreneurs and investors are leading the way in the development of these products and services.

To address this emerging area, Duane Morris developed a multidisciplinary client team whose members are experienced in addressing the legal issues that clients must consider in developing, funding or deploying a product or service that could be considered mHealth or telemedicine, or that relies on HIT.



U.S. NEWS-BEST LAWYERS 2021
Best Law Firms awarded Duane Morris top-tier national ranking in Health Care law.

RANGE OF SERVICES

- ▶ GOVERNMENT AND PRIVATE PAYOR REIMBURSEMENT
- ▶ PRIVACY AND SECURITY REQUIREMENTS, INCLUDING BREACH RESPONSES, UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) AND STATE LAWS
- ▶ FOOD AND DRUG ADMINISTRATION (FDA) REVIEWS FOR DEVICES
- ▶ INTELLECTUAL PROPERTY (IP) ISSUES
- ▶ PRACTICE OF MEDICINE CONCERNS
- ▶ CORPORATE FORMATION, OPERATION AND GOVERNANCE
- ▶ FRAUD AND ABUSE ISSUES
- ▶ FEDERAL COMMUNICATIONS COMMISSION (FCC) OVERSIGHT

SIGNIFICANT MATTERS

- ▶ Provided corporate and regulatory support concerning HIPAA, Meaningful Use regulations and licensing for an **ENTERPRISE-BASED, COMMUNITY-WIDE HEALTH INFORMATION ORGANIZATION/EXCHANGE (HIO)** for a 1,500-bed health system connecting hospitals' Electronic Health Record (EHR) system with employed and non-employed physicians and mobile applications and devices used in the health system.
- ▶ Represented as general corporate counsel a company that produces a **MOBILE EKG DEVICE** that attaches to the body and transmits data for diagnosis, prevention and monitoring of cardiovascular disease. The data from the device are analyzed, and the analysis is transmitted back to the physician, emergency room staff, and/or first responders.
- ▶ Provided corporate and regulatory support concerning assumption of risk and consent documents and privacy issues for a company providing **CLINICAL DECISION SUPPORT SOFTWARE** using evidence-based risk assessment tools to assist case managers in making data-driven decisions at discharge.

- ▶ Represented with regard to corporate and regulatory support a **PHARMACY BENEFIT MANAGEMENT (PBM) SOLUTIONS COMPANY** that produces software to assist healthcare safety net organizations in managing discount drug programs, saving money and expanding access by searching pricing options to assure that health centers, hospitals, payors and patients always pay the lowest price for medications.
- ▶ Represented a company in connection with a patent portfolio covering **"SMART TRAY" TECHNOLOGIES** for intelligent delivery, tracking and dispensing of prescription medications, wherein each tray contains a predetermined number of pills in bulk form, as well as the necessary electronics and memory for communicating with external devices, such as large dispensing machines configured to receive many smart trays in designated slots of the dispensing machine.
- ▶ Represented a medical center with licensing issues concerning a **HOSPITAL-BASED EHR SYSTEM AND SOFTWARE**.
- ▶ Prepared a licensing agreement for a burn center application that uses **TELEMEDICINE TO CONNECT COMMUNITY HOSPITALS WITH BURN CENTER SPECIALISTS** for coordination of care.
- ▶ Represented a healthcare management company with regard to drafting an assumption of risk and release of liability agreement concerning an **APPLICATION DESIGNED TO DEMONSTRATE REHABILITATIVE EXERCISES AND THERAPIES** and track patient process.
- ▶ Designing **MEDICARE DOWNSTREAM AND HIPAA PRIVACY & SECURITY COMPLIANCE PROGRAMS** for a private equity-backed media group that provides medical content and direct mail services for payor education programs, e-prescribing and discharge medical content (e.g., dosage information) for providers, and medical content through mobile applications.
- ▶ Represented **THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA (HAP)** with respect to patent infringement issues against EHR vendors, hospitals, pharmacies and other providers.
- ▶ Advised and redesigned the overall business plan, prepped the client on investor pitches and designed specific reimbursement strategies for a healthcare information technology company providing a **PLATFORM AND MOBILE DEVICE SYSTEM TO SUPPORT SECURE PHYSICIAN-PATIENT AND PROVIDER-PROVIDER COMMUNICATIONS**.
- ▶ Advised a healthcare technology company on business strategies, negotiated strategic relationships and developed new product strategies for **MOBILE PATIENT EDUCATION PRODUCTS**.
- ▶ Represented **EYEIC, INC.**, a startup company that provides web-based FDA-approved eye image comparison technology to support clinical care, patient education, claims submission and documentation, in connection with its general corporate and securities matters, capital raising efforts, strategic relationships and labor and employment matters.
- ▶ Advised **ADFLOW, INC.** on corporate and healthcare issues (corporate practice of medicine, advertising, FDA) for their patented technology platform that provides consumer-oriented healthcare solutions and offers advanced digital signage capabilities. Also provided advice regarding general corporate and securities matters, capital raising, strategic relationships and labor and employment matters.
- ▶ Represented **REALTIME MEDICINE, LLC**, a startup company seeking to develop a telemedicine service in Texas on a private pay-only basis, with regard to contract review and analysis of potential Texas and federal law issues.
- ▶ Represented a healthcare technology company in providing FDA, privacy and security compliance support for a **MOBILE HEALTH APPLICATION TARGETED AT CARDIAC CONDITIONS**.
- ▶ Represented a healthcare technology company in providing privacy and security compliance support for an application targeted for **PRESCRIPTIONS AND MOBILE HEALTH WELLNESS SUPPORT FOR DIABETES**.
- ▶ Represented a long-term care pharmacy in providing privacy and compliance support for a mobile health application providing **LONG-TERM CARE PHARMACY SUPPORT**.
- ▶ Prepared and prosecuted U.S. and international patent applications for **OMNYX, LLC** in their integrated digital pathology systems, which have network coupled pathology and histology workflow management systems, microscope slide scanners and user workstations, allowing the pathologists to navigate, pan, zoom, annotate and process a whole slide image over a data network.



FOR MORE INFORMATION, PLEASE CONTACT:

NEVILLE M. BILIMORIA, Partner

Duane Morris LLP

190 South LaSalle Street, Suite 3700

Chicago, IL 60603-3433

312.499.6758 | nmbilimoria@duanemorris.com

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