

Digital Health

To view an image showing our areas of focus under Digital Health, [click here](#).

Polsinelli's digital health practice uses an integrated approach to address digital health service needs. Digital health encompasses a diverse set of products, services and organizations applying technology and data to health care. Polsinelli applies an integrated, multispecialty approach to address the full range of digital health client needs. Business success in digital health requires comprehensive understanding of a range of legal, business and other issues in today's rapidly changing environment.

Our clients include new and established health care companies and providers, technology and other organizations engaged in developing and deploying digital health innovations to health-related problems and needs, and other entrants into this rapidly changing field.

Polsinelli's digital health practice advisors combine specialized knowledge in law and policy, with industry-informed practical experience. Our integrated digital health practice involves advisors with proficiency in the critical issue areas listed below.

Generating Revenue

Polsinelli's advisors in health care delivery, operations and related fields help digital health clients to navigate our nation's health care delivery and payment systems, while collaborating with other advisors in a multidisciplinary, integrated approach to meet client service needs. Our lawyers and other advisors work with new and established digital and health care provider organizations to integrate digital health technologies, products and services into our nation's health care delivery ecosystem. Our attorneys and advisors are skilled in translating and applying Federal and State laws, rules, guidelines and precedent to today's burgeoning digital health field. Polsinelli applies a multispecialty approach to address the full range of digital health client service needs.

Many technology companies and innovators are adept at developing new products and services that use technology and data to influence human health. However, business success frequently requires understanding, navigating and continually adapting to the extensive patchwork of laws and rules currently governing health care delivery, reimbursement and compliance. Our advisors have extensive experience in all facets of health care delivery system organization, operations and reimbursement, including:

- Health care service delivery licensure and related requirements
- Business structure and operational requirements
- Provider credentialing, reimbursement and payment under public and commercial payor arrangements
- Application of HIPAA, GDPR, CCPA and other federal and state requirements to health care and other data
- Fraud and abuse, compliance and litigation support

Designing & Scaling a Business

Polsinelli business and finance advisors integrate with the firm's multidisciplinary digital health practice to promote effective business structure, finance, operations, M&A and related strategies. Businesses involved in digital health must address business fundamentals including structure, access to capital, tax and related variables, while operating at the intersection of rapidly changing, technology, health care, privacy, data commercialization, intellectual property, private equity/corporate finance and other sectors.

Polsinelli's business lawyers integrate with the firm's digital health practice in addressing the full range of digital health business needs. Our clients include new and established companies involved in technology, health care and other entities engaged in the development, deployment and use of digital health innovations to health-related problems and needs.

Digital health businesses operate in complex, highly competitive and rapidly changing environments. Businesses working in this space must be structured and operated in the context of evolving market demands, consumer preferences and legal and regulatory requirements. Teams led by Polsinelli business lawyers, working in collaboration with subject matter specialists in technology, IP, health care, privacy and other fields provide a multispecialty perspective to digital health company needs.

Digital health businesses are commonly disruptive in deploying new technologies, products and services in a changing market-place. Yet these businesses must be formed, financed, operated, merged and sold through the use of well-established form of entity, securities, tax, transactional and other strategies.

Securing & Protecting Ideas

Polsinelli has a long history of working closely with clients, including Fortune 500 companies, mid-size public and private companies, start-ups, universities and nonprofit research institutes, to provide protection, enforcement and monetization strategies for their digital health copyright, patent, trademark, trade secret and proprietary IP assets.

Whether a client needs patent, trademark and copyright filings, transactional assistance, a team of seasoned litigators, opinion work, handling of USPTO proceedings or just everyday advice, our deep bench of IP professionals have the experience to meet those needs, particularly with respect to digital health technologies including:

- Telehealth/telemedicine
- Personalized medicine
- Digital therapeutics
- Wearable and implantable technology
- Artificial intelligence and cognitive computing
- System-level platforms and cloud computing
- Electronic health/medical records
- Big data, bioinformatics and genomics
- Health data consumerism and sharing
- Scheduling solutions
- Social/community networks
- Online fitness
- Information blocking
- Body networks
- 3D printing (medical devices and pharmaceuticals)
- Health and medical software applications
- Automated medical treatment devices and sensors
- Nanotechnologies
- Virtual reality and assistive technologies

Obtaining Approvals & Influencing Policy

Polsinelli works with innovators as they develop and/or partner with digital health platforms and help navigate legal and regulatory issues that arise by effective advocacy before Members of Congress, Congressional Committees, the U.S. Department of Health & Human Services, U.S. Food & Drug Administration and other agencies. Our attorneys and public policy advisors have served in the U.S. Congress, as staff in the U.S. House and U.S. Senate, and as Congressional liaisons for national medical trade associations and technology companies. On the administrative side, our team also specializes in advocacy before the FDA, CMS and regional Medicare Administrative Contractors (MACs).

Our Public Policy group provides strategic advocacy counsel and leads multi-stakeholder advocacy campaigns to advance the interest of our digital health clients.

Our Food & Drug Law team counsels clients on U.S. Food & Drug Administration review, including guidance related to mobile medical devices, pre-certification and marketing.

We provide strategic guidance to clients seeking Medicare coverage and payment, including direct advocacy before the Centers for Medicare & Medicaid Services (CMS), to secure favorable policies within the Medicare Physician Fee Schedule and other payment rules and for appropriate federal payor coverage.

Commercializing Technology & Data

We structure, draft and negotiate technology agreements for health care institutions developing, acquiring or deploying the technologies that make up digital health. Our team handles AI, Machine Learning, data analytics and ownership, use and sharing of data for patient care, research and hospital operations, and we assist technology companies in developing the commercializing and protecting digital health technologies.

Our lawyers combine health care-specific industry knowledge with experience in technology and data in other industries to provide comprehensive legal counseling. We handle the underlying IT agreements and data systems that support digital health technology.

Our representation of technology companies and health care institutions gives us actionable-insights into the issues from all points of the compass. The matters we handle include the following:

- Taking digital health solutions from proof of concept to full deployment
- Joint ventures and technology development agreements
- Connecting on-premises and cloud computing
- Using edge computing
- AI and machine learning
- Data analytics
- Using data fabrics and other IT solutions to provide a unified stream of data for analytics
- Natural language processing
- Alexa and voice assistance
- Implantables and wearables
- IoT and other connected devices
- Software-as-a-Medical Device
- Body area networks and robotic technology
- Biometrics
- Telehealth and virtual hospitals

Promoting Compliance & Negotiating Challenges

Polsinelli compliance and litigation advisors assist digital health clients in avoiding regulatory risk, and in defensive and offensive postures relative to fraud and abuse, privacy, intellectual property and business-related challenges. The rapid growth of new digital health technologies, companies and business models has resulted in

unprecedented compliance risks and challenges under new and well-established laws and liability theories, particularly with regard to the incredibly valuable data that drives it all.

Polsinelli's deep bench of lawyers with significant compliance, enforcement, litigation and defense experience in key sectors at the heart of digital health. Our multidisciplinary teams bring together attorneys specializing in privacy, security, cybersecurity, technology and litigation, including former leaders of HIPAA Compliance and Enforcement for the Office for Civil Rights (OCR) and within the U.S. Department of Justice. Our experienced team has a proven track record of advising, defending and prosecuting actions related to digital health such as:

- HIPAA, FERPA and federal laws governing confidentiality of alcohol and drug abuse treatment records
- State privacy/security laws related to the health information confidentiality, including California
- Data Privacy Regulation, laws governing mental health, HIV/AIDS and genetic information
- GDPR and other international privacy laws impacting data use and transfers
- Federal fraud and abuse laws including the Anti-Kickback Statute, Stark Law, False Claims Act
- State-specific telemedicine and related laws
- Intellectual property prosecution and defense related to digital health technologies and innovations
- Product liability, employment, antitrust, payment and other business disputes

Matters

Health Care Delivery & Operations

- Advising on business and contractual arrangements related to the delivery of health care services using digital health, including navigating state licensure, scope of practice, corporate practice of medicine and other laws impacting business and service delivery arrangements.
- Assisting with health care operations, enrollment, payment, and fraud and abuse law compliance.
- Assisting health care providers in telehealth, telemedicine and remote patient monitoring strategies, including in connection with operations, reimbursement, regulatory, fraud and abuse and other compliance issues.

Business/Finance/Operations

- Structuring, buying, selling and contracting with organizations engaged in digital health care.
- Advising new/start-up and established technology and service companies on legal and tax-structure, M&A, finance/capitalization and related matters.
- Driving M&A transactions involving digital health assets, including addressing key due diligence, representation and warranty and indemnity considerations in the rapidly evolving digital health field.
- Addressing digital health company business operational needs including founder and key employee compensation and incentives, immigration, wealth planning and related needs.

Intellectual Property

- Developing, protecting, deploying and using digital health technologies and intellectual property.
- Contracting, licensing and marketing.
- Assisting technology, medical device and other companies on patent, copyright, trademark and other IP-related prosecution and defense strategies.
- Serving as lead IP counsel in utility patent, design patent and trademark litigations involving cutting edge technologies, including fitness equipment and orthodontic treatment devices.

Public Policy/Advocacy

- Assisting with FDA, health care payment/reimbursement and public policy strategies.
- Advising and assisting clients on FDA clearance, medical device and other software and technology-related issues.
- Undertaking Federal-level advocacy with CMS and the U.S. Congress on behalf of technology and digital health companies, health care providers and other organizations to achieve payment and reimbursement for services furnished through the use of digital health.

Technology & Data

- Advising and negotiating on IT agreements and data systems that support Digital Health technology.
- Assisting health care providers, technology vendors and other organizations in planning for and integrating contractual, data commercialization and other strategies into technology arrangements.
- Supporting innovative companies and developers in addressing the protection, deployment and commercialization of products and services in the digital health and related spaces.

Compliance & Litigation

- Counseling and defending liability risks related to privacy, cybersecurity, intellectual property, products liability, fraud and abuse, government investigations and business disputes.
- Defending telehealth, technology and other companies on regulatory compliance matters including government investigations, HIPAA/privacy and security, fraud and abuse, and other litigation related matters.
- Advising on cybersecurity contractual, insurance and related strategies for digital health companies and users.

Publications

July 18, 2025

Regulatory Trend: Safeguarding Mental Health in an AI-Enabled World

February 6, 2025

Generative Artificial Intelligence Leveraged to Deliver Healthcare - Legal Risks and Issues

May 10, 2023

Proposed Regulatory Oversight on the Emerging Use of Artificial Intelligence in Digital Health

May 9, 2023

DEA Temporary Rule Extends Telemedicine Flexibilities Through November 2023 and Grants Additional One-Year Grace Period