Melissa K. Bianchi

Partner
Washington, D.C.

Biography

Melissa Bianchi leads the firm's digital health initiative, bringing together a cross-disciplinary approach to digital health products such as mobile apps, wearable sensors, and other health IT solutions. Well versed in health privacy law, she helps clients navigate a range of complex health data issues under the Health Insurance Portability and Accountability Act (HIPAA) and other U.S. laws.

Melissa advises companies and academic medical centers on cutting-edge clinical research issues, genetic information, and tissue and data repositories. She handles health information exchange and meaningful use issues for hospitals and their vendors, and works closely with a number of academic medical centers on structuring research activities under HIPAA, managing student health centers, and general HIPAA compliance.

Melissa understands the health data issues unique to biotech and pharmaceutical companies. She also has a deep knowledge of – and speaks extensively about – prescription drug coverage under health reform and Medicaid expansion. Since passage of the Medicare Part D program, she has been advising drug companies on coverage issues and also helps health plans with compliance.

Representative experience

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Practices

Health Law

Privacy and Cybersecurity

Industries

Life Sciences and Health Care

Areas of focus

Digital Health

Clinical Trials

California Consumer Privacy Act

Health Privacy and Cybersecurity

Outside privacy counsel to a global pharmaceutical company on social media recruiting of clinical trial participants.

Advise biotechnology company on use of mobile devices in clinical trial and ongoing patient support programs.

Policy advisor to large trade association on health reform and Medicaid prescription drug coverage.

Representing a large health information technology company on privacy, data sharing, contracting, and data breach management.

Advises academic medical center on clinical trial data breaches.

Representing pharmaceutical companies and providers in matters involving Medicare prescription drug coverage.

Conducted privacy assessment of online information practices for a Fortune 500 global pharmaceutical company.

Primary outside counsel to major university on HIPAA and clinical research compliance.

On behalf of major trade associations and individual clients, advocated for meaningful prescription drug coverage under health reform.

Advised multiple universities on structuring compliance for student health centers.

Advise major pharmaceutical company in assessment of privacy compliance in patient support programs.

Awards and rankings

- Healthcare: Health Insurers, *Legal 500 US*, 2014
- Technology: Data Protection and Privacy, *Legal 500 US*, 2013 - 2014
- Outstanding Young Healthcare Lawyers, *Nightingale's*

Education and admissions

Education

J.D., Stanford Law School, 1999

A.B., Harvard University, magna cum laude, 1992

Bar admissions and qualifications

District of Columbia

California (inactive)

Latest thinking and events

- Hogan Lovells Publications
  - Life sciences and health care horizons 2021

- News
  - Top 10 things biotech employers need to know about COVID-19 vaccines and returning to the office

- Webinar
  - What biotech employers need to know about COVID vaccines and returning to the office

- News
  - HHS proposes changes to key provisions of the HIPAA Privacy Rule

- Sponsorships and Speaking Engagements
  - FDA Regulation of Digital Health and Recent Medicare Updates

- News
  - Trump Administration revives rebate safe harbor rule in late effort to reform drug pricing