FOLEY & LARDNER LLP

Alexandra B. Maulden

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Alexandra (Alex) Maulden is a health care lawyer with Foley & Lardner LLP and a member of the firm's Health Care Practice Group. Alex's practice focuses on a broad range of federal and state regulatory compliance and business matters for health industry clients, including hospitals, health systems, provider practice groups, long-term care facilities, clinical laboratories, and telemedicine companies.

Alex has experience providing federal and state regulatory compliance guidance specifically related to fraud and abuse laws including anti-kickback statutes, physician fee-splitting statutes, and physician self-referral laws, as well as state licensure rules, government and commercial reimbursement issues, federal DEA and state-controlled substances laws. Her practice also includes conducting internal investigations, and operational matters like drafting contracts and compliance policies. In particular, Alex counsels clients in the substance use disorder space on licensing, regulatory compliance, general business matters, and the intersection of state and federal law. Drawing on her background in clinical research, Alex has also assisted in the development and maintenance of clinical trial compliance programs, and has drafted and reviewed clinical trial agreements and corporate policies on behalf of institutions, contract research organizations, and pharmaceutical clients.

During law school, Alex was selected for the Mayo-Foley Health Law Fellowship, consisting of summer internships with the Mayo Clinic Legal Department in Rochester, Minnesota and Foley's Boston office. During this time, she assisted attorneys at both the Mayo Clinic and Foley with a broad range of regulatory compliance and transactional matters. While in law school, she also interned with the Whistleblower Law Collaborative where she researched a variety of issues relating to health care fraud and abuse, with a specific focus on the Coronavirus Relief Fund.

Before law school, Alex was a clinical research assistant in the Emergency Department at Boston Children's Hospital, where she coordinated with medical staff to identify eligible research study patients and discussed study procedures with patients.

Presentations and Publications

- Co-author, “FDA & OHRP Draft Guidance: Including Tissue Biopsies in Clinical Trials,” *Health Care Law Today* (Fenruary 3, 2025)
- Co-author, “DEA Tightens Buprenorphine Telemedicine Prescribing Rules,” *Health Care Law Today* (January 16, 2025)
- Co-author, “Medicare Telehealth Flexibilities Get a Three-Month Lifeline,” *Health Care Law Today* (December 23, 2024), republished in *Chicago Medicine’s* February 2025 issue
- Co-author, “FDA Clinical Investigations: New Guidance on Electronic Systems,” *Health Care Law Today* (November 20, 2024)
- Co-author, “Substance Use Disorder Treatment Services: 2025 Physician Fee Schedule Proposed Rule Would Expand Access and Medicare Coverage,” *Health Care Law Today* (July 29, 2024)
- Co-author, “Clinical Trials: FDA Publishes Draft Guidance on Diversity Action Plans,” *Health Care Law Today* (July 25, 2024)
- Co-author, “New Favorable OIG Advisory Opinion Allows Patient Assistant Programs Funded by Drug Manufacturers,” *Health Care Law Today* (April 25, 2024)
- Co-author, “FDA Issues New Warning Regarding Compounded Ketamine,” *Health Care Law Today* (October 26, 2023)
- Co-author, “Gender Affirming Care in Florida: Current Rules of the Road,” *Health Care Law Today* (August 23, 2023)
- Co-author, “Gender Affirming Care Restricted Under Missouri Bill,” *Health Care Law Today* (May 16, 2023)
- Co-author, “Florida’s Bill Targeting Gender Affirming Care Impacts Minors and Adults,” *Health Care Law Today* (May 9, 2023)
- Co-author, “FDA Publishes Framework for Digital Health Technologies in Clinical Trials,” *Health Care Law Today* (April 3, 2023)
- Author, “Ignoring the Experts: Implications of the FDA’s Aduhelm Approval” 48 American Journal of Law and Medicine 108-133 (July 11, 2022)
- Co-author, “United States,” *The Healthcare Law Review* (July 30, 2021)
- Author, “Wearables and the FDA: Lessons from the COVID-19 Pandemic,” DOME BLOG (June 28, 2021)
- Co-author, “11th Circuit FCA Ruling Takes Practical Approach to Materiality,” *Law360* (July 8, 2020)
- Co-author, “Diagnostic Performance of C6 Enzyme Immunoassay for Lyme Arthritis,” *Pediatrics* (January 1, 2020)
- Co-author, “Positive 2-Tiered Lyme Disease Serology is Uncommon in Asymptomatic Children Living in Endemic Areas of the United States,” *Pediatric Infectious Disease Journal* (May 2019)
- Author, “Two-tier Lyme Disease Serology Test Results Vary By First-tier Test,” *Pediatric Journal of Infectious Disease Society* (February 22, 2019)

- Co-author, “C-Reactive Protein or Erythrocyte Sedimentation Rate Results Reliably Exclude Invasive Bacterial Infections,” *The American Journal of Emergency Medicine* (November 8, 2018)
- Co-author, “Accuracy of Clinician Suspicion of Lyme Disease in the Emergency Department,” *Pediatrics* (September 21, 2017)

Sectors

- Health Care & Life Sciences
- Medical Devices
- Pharmaceuticals
- Providers of Health Care Services

Practice Areas

- Corporate
- False Claims Act
- Health Care

Education

- Boston University School of Law (J.D., cum laude, 2022)
  - Concentration in Health Law with Honors
  - Senior Articles Editor, *American Journal of Law and Medicine*
  - Vice President, Health Law Association
- Colgate University (B.A., 2016)
  - Beta Beta Beta National Biological Honor Society

Admissions

- Massachusetts