



Michael A. Dowell

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With more than 30 years of experience, Michael Dowell provides regulatory and transactional counsel to a variety of healthcare industry sectors, including federally qualified health centers (FQHCs), pharmacies—including retail, multi-state, wholesale distributors, specialty, mail order, veterinary, compounding, long-term care, and pharmaceutical manufacturers, telemedicine and digital health providers, managed care plans including Medicaid Managed Care Plans and Medicare Advantage Plans, physician organizations, MSOs, and ancillary service providers.

Michael advises clients on federal and state laws, including:

- Section 330 of the Public Health Service Act
- HRSA Health Center Program Requirements, including Scope of Project and, HRSA Operational Site Visits (OSVs)
- Federal Tort Claims Act
- State Boards of Pharmacy Practice Acts
- FDA Drug Quality and Security Act and the Drug Supply Chain Security Act
- DEA Controlled Substances Act and Regulations
- Data Privacy and Security (HIPAA and HITECH)
- Corporate Practice of Medicine, Fee-splitting, and Scope of Practice Restrictions
- Anti-kickback, Self-Referral and Civil Monetary Penalties Laws
- Health Care Provider and Facility Licensure Requirements
- Medicare and Medicaid Enrollment and Reimbursement Rules
- Managed Care Plan Licensure and Operational Laws

Michael frequently represents clients before state agencies and state professional boards such as the California Department of Health Care Services, the California Department of Public Health, the Office of Administrative Hearings, as well as before the FDA, DEA, OIG, CMS, and HRSA.

Professional Affiliations

- American Health Lawyers Association
- American Society for Pharmacy Law
 - Board of Directors

Practices

Business & Commercial Transactions
Privacy, Security & Artificial Intelligence
Mergers & Acquisitions

Industries

Cannabis
Health Care
Health Care Corporate Transactions
Health Care Information, Privacy & Security
Health Care Operations
Health Care Pharmacy
Health Care Regulations & Compliance

Education

J.D., Indiana University Maurer School of Law
B.S., Pharmacy, Purdue University

Admissions

California
Indiana



- California Society for Healthcare Attorneys
 - Board of Directors
 - Education Committee
 - Diversity Committee
- California Pharmacists Association
- Los Angeles County Bar Association
 - Health Law Section, Past Chair

Honors & Awards

- Recognized as a "[Top Health Care Lawyer](#)" in California by *The Daily Journal*, 2022

Representative Matters

Some of Michael's representative matters and transactions include:

Federally Qualified Health Centers (FQHCs)

- Establishment of FQHCs, including preparation of organizational matters, community license applications and federal qualification, board governance, conflicts of interest, and tax-exempt organization requirements.
- Conducted pre-HRSA visit surveys and site visit preparation and assistance with corrective actions and responses regarding HRSA site visit and audit findings.
- Counseled multiple FQHCs on mergers, acquisitions, joint ventures, affiliations, and contracts.
- Represented clients regarding Medicare and Medi-Cal enrollment, overpayments, PPS reconciliation, PPS audits, costs reports, and other audits and investigations.
- 340B Drug Program compliance counseling for covered entities.
- Development and regulatory counseling of Program of All-Inclusive Care for the Elderly (PACE Programs).

Pharmacy Law

Michael represents clients on pharmacy regulatory matters, including licensing, contracts, transactions, and litigation—civil, administrative, and appeals. Michael is a pharmacist, and his career as a pharmacist included employment in chain store, independent, and inpatient hospital pharmacies. His knowledge of the pharmacy industry provides him with the tools to represent pharmacy industry clients in all 50 states.

- Handled pharmacy license, permit applications, change of control requests, board disciplinary matters and petitions for reinstatement, administrative hearings, and administrative writs with all 50 State Boards of Pharmacy.
- Represented clients in multi-state mergers, acquisitions, and dispositions of pharmacies, pharmacy wholesalers, and pharmacy manufacturers.
- Prepared Medicare and Medi-Cal enrollment applications and defended governmental audits, suspension orders, and termination appeals.
- Drug Enforcement Administration (DEA) and Controlled Substances Act compliance counseling, audits, investigations, and defense.
- Provided advice and counsel to multiple clients regarding PBM contracting, audits, and dispute resolution – withholds, appeals, invoice shortages, mail orders, and credentialing.
- 340B Drug Program compliance counseling for contract pharmacies.



Health Care Transactions and Regulatory Matters

- Represent buyers, sellers, and investors in all aspects of the sale, purchase, merger or joint venture of multi-state pharmacies, management companies and affiliated medical and dental practices, hospitals, health care systems, medical groups, clinics, ambulatory surgery centers, and ancillary service providers.
- Represent providers before state and federal regulatory bodies, including drafting voluntary disclosures, settlement agreements, and providing assistance with state regulatory agency, CMS, DEA, FDA, HRSA, and OIG audits and investigations.
- Knox-Keene Health Care Services Plan (HMO, PPO, and EPO) licensure and regulatory advice, including the formation of Medicare Advantage Plans and Medicaid HMOs.
- Advised numerous health care providers and entities regarding fraud and abuse matters, including federal and state Anti-Kickback Law, Self-Referral Law Prohibitions, and False Claims Act liability risks and compliance.

Telemedicine and Telehealth

- Provided advice and counsel to multiple telemedicine and telehealth companies, entrepreneurs, investors, and institutions on a broad range of telemedicine and telehealth legal issues.
- Represented a health system with an electronic health records software physician donation program, data privacy, and security issues.
- Represented a national mail order pharmacy in providing pharmacy fulfillment services for telemedicine companies.
- Represented a long-term care pharmacy in providing data aggregation and data analytics, 340B specialty pharmacy, and telemedicine services for FQHCs and rural health centers.
- Prepared telemedicine contracts that addressed medical practice, scope of practice, tele-prescribing and licensure requirements.

Presentations

Michael speaks regularly to many organizations, including the American Association of Health Plans, American Health Lawyers Association, California Association of Health Plans, National Dental Association, State Bar of California, and the Health Care Law Section of the Los Angeles County Bar Association. His presentations include:

- "Using the Federal Tort Claims Act Program to Preserve Limited Financial Resources," Illinois Primary Health Care Association, Annual Leadership Conference, Schaumburg, Illinois, October 6, 2023
- "Federally Qualified Health Center Mergers and Acquisitions," Illinois Primary Health Care Association, Annual Conference, October 2020
- "Telehealth is Essential For Health Centers: Today and Beyond," Illinois Primary Health Care Association, Annual Conference, October 2020
- "340B Drug Program Challenges and Opportunities," Nevada Primary Care Association's (NPCA) Virtual 2020 Annual Health Care Conference, Virtual Event, September 16, 2020

Publications

- "[DEA Compliance Update](#)," U.S. Pharmacist, Pharmacy Law, January 14, 2024;49(1):9-12
- "[Ruling Increases Pharmacy False Claims Act Risks](#)," U.S. Pharmacist, Pharmacy Law, September 18, 2023;48(9):7-12
- "[DEA Must Prove 'Knowing and Intentional' Violations of the Controlled Substances Act](#)," U.S. Pharmacist, Pain Management, November 18, 2022;47(11):32-25
- "[State PBM Regulations Protecting Community Pharmacies](#)," U.S. Pharmacist, Pharmacy Law, August 16, 2022;47(8):21-25



- ["Pharmacies Must Take Steps to Protect Against Data Breaches,"](#) U.S. Pharmacist, Pharmacy and Technology, May 13, 2022;47(5):34-38
- ["DEA Inspections and Audits Warrant Compliance Plan, Part 2,"](#) *Compliance Today*, December 2019
- ["DEA Inspections and Audits Warrant Compliance Plan, Part 1,"](#) *Compliance Today*, November 2019
- ["Compliance Tips on How to Pass State Board of Pharmacy Inspections,"](#) *Journal of Health Care Compliance*, September/October 2019
- ["Federally Qualified Health Center and Rural Health Center Telemedicine Compliance and Legal Issues,"](#) *Journal of Health Care Compliance*, March/April 2019
- ["OIG Issues New Safe Harbor on Free or Discounted Local Transportation Services,"](#) BNA's *Health Care Fraud Report*, February 2017
- ["California Appellate Court Upholds Pharmacist-In-Charge Responsibility for Pharmacy Technician \\$1 Million Drug Theft,"](#) *California Pharmacist Magazine*, Winter 2016
- ["Recent OCR Enforcement Actions Emphasize the Importance of Executing HIPAA Business Associate Agreements,"](#) BNA's *Health Law Reporter*, June 2016
- ["HIPAA Settlement with Community Pharmacy Highlights Best Practices for the Handling and Disposal of Paper PHI,"](#) BNA's *Health Law Reporter*, May 21, 2015
- Co-Author, ["Federally Qualified Health Center and Look-Alike Sliding Fee Discount and Related Billing and Collections Program Requirements,"](#) *Journal of Health Care Compliance*, January/February 2015