# HINSHAW

# Health Care Pharmacy

## Drugs have a limited shelf life. Businesses don't. Hinshaw helps clients succeed over the long term.

Today's pharmaceuticals are more effective—and more complex—than ever. The same is true for the pharmaceutical and pharmacy industries. Drug companies and individual pharmacists alike can have a tremendous, positive impact on the lives and health of their patients. But the regulatory hurdles they must leap and the financial and businesses challenges they must overcome often seem to complicate, rather than simplify, the path toward success.

At Hinshaw, we know that effective legal counsel is like good medicine: it must be offered at the right time and in the right amount. Our health care lawyers have experience advising a broad range of industry clients—from individual pharmacists and small business owners providing one-on-one patient care—to major, multinational pharmaceutical companies whose research into innovative drugs and treatment protocols will have lasting, global effects.

We serve pharmaceutical clients throughout the lifecycle, beginning with basic research and clinical trials, through marketing and distribution, to prescription and sale. Our lawyers understand the regulatory, legal and business issues that arise at each of these steps and provide effective counsel that helps resolve immediate challenges while also setting the stage for future success. We advise clients on the following:

- Research and drug trials
- Patents, trade secrets, and other IP prosecution and enforcement
- Licensure, operations and regulatory compliance
- Medicare Advantage and Part D Program requirements, including reimbursements and pricing
- HIPAA, HITECH Act, and related federal and state data privacy and security requirements
- Mergers, acquisitions, joint ventures and other business transactions
- Board disciplinary administrative complaints and administrative hearings
- Drug Enforcement Agency (DEA) matters
- Payor audit appeals and investigation defense
- Audits and internal investigations
- Professional and product liability defense

Our experienced health care litigators also counsel clients in the full range of commercial disputes. We provide outcome-driven representation, whether negotiating across the settlement table or presenting a strong defense in court.

#### **Attorneys**

Sara Butler Michael A. Dowell Frank A. Mazzagatti, Ph.D.

#### **Related Industries**

Health Care

Health Care Corporate Transactions

Health Care Defense

Health Care Human Resources

Health Care Information, Privacy & Security

Health Care Operations

Health Care Regulations & Compliance



#### News

Scott Seaman Recognized as a Top Insurance Author in JD Supra 2024 Readers' Choice Awards March 4, 2024

Michael Dowell Discusses Impact on Pharmacies of U.S. Supreme Court Ruling that DEA Must Prove Knowing and Intentional Violations of the CSA December 8, 2022

Michael Dowell Recognized as a Top Health Care Lawyer by The Daily Journal November 21, 2022

Michael Dowell Discusses State Regulatory Scrutiny of Pharmacy Benefit Managers September 13, 2022

Michael Dowell Discusses Cybersecurity and Cyberattack Prevention Strategies for Pharmacies May 16, 2022

### Publications

California Prohibits PBM Discriminatory Practices Against 340B Program Covered Entities and Contract Pharmacies December 15, 2023 Health Care Alert

California Expands "No Pharmacist Left Alone" Pharmacy Staffing Requirements and Also Enacts New Safety Measures November 17, 2023 Health Care

Laboratory Testing Presents Business Opportunities for Community Pharmacies January 11, 2022 Health Care Alert

New California Law Prohibits Chain Community Pharmacy Productivity Quotas for Pharmacists and Pharmacy Technicians October 27, 2021 Health Care Alert

Change is on the Horizon for 340B Pharmacy Program's Administrative Dispute Resolution Process December 21, 2020 Health Care Alert

Attention Pharmacies and Prescribers: New California Controlled Substances Prescription Form and CURES Reporting Requirements Are Coming November 19, 2020 Health Care Alert

California Board of Pharmacy Approves "No Pharmacist Left Alone" Regulations for Retail Pharmacy Chains

September 21, 2020 Health Care Alert

Federally Qualified Health Center Agrees to Settlement for Failure to Implement

August 26, 2020 Health Care Alert

OPA Program Update 2020 Highlights Changes to 340B Program Registration and Recertification Requirements August 13, 2020

Health Care Alert



Guidance for Protecting Pharmacy Staff and Customers from COVID-19 May 14, 2020 Health Care Alert