

Health Care, Life Sciences, Pharmaceutical and Public Health Preparedness

Overview

Work with our Dentons' Government Contracts group and policy advisors, who are leaders in health care law and who operate at the intersection of health care and government. You will be counseled on a broad spectrum of health care matters, ranging from the completion of basic transactions, including clinical trial agreements and mergers and acquisitions, to the guidance and support necessary to successfully maneuver the more intricate and complex situations that often arise in the health care industry.

Our Government Contracts lawyers are authorities on federally funded health care programs, including Medicare, Medicaid, Tricare, the Federal Employee Health Benefits Program and related drug-pricing issues, as well as health care exchanges. This experience is coupled with their understanding of government contracts law and regulation and of contract obligations. Working with the Health Care regulatory team, our Government Contracts lawyers are uniquely situated to handle any manner of health care-related issues.

Rely on us to help you skillfully confront matters, whether transactional, regulatory or litigation-specific. We will help you handle every aspect of health care advocacy, cutting across practice areas and pooling Dentons' resources to present you with comprehensive support. From regulatory affairs to litigation to public-private partnerships, you will receive premier service when it comes to criminal and civil fraud defense of pharmaceutical and medical device companies, as well as defense of alleged violations of the US Food, Drug and Cosmetics Act (FDCA), anti-kickback, off-label marketing and fraudulent pricing matters. We will help you navigate the peculiarities and minefields of applicable federal law.

Benefit from a team that blends together legal experience with industry knowledge and includes professionals with PhDs in chemistry and mechanical engineering, as well as a former lawyer with the Food and Drug Administration (FDA), and other professionals with backgrounds in government affairs and federal, state and local regulatory agencies. We help you grasp the complex legal and regulatory obstacles confronting health care organizations today, especially in the current political climate that is calling for health care reform.

Relevant experience includes:

- Successfully litigated Tricare bid protests over the award of the Tricare West Region contract
- Successfully litigated MAC bid protests
- Responded to audits of Medicare contract performance and administration
- Represent pharmaceutical and life sciences clients in all manner of dealings with the Biomedical Advanced Research and Development Authority (BARDA)
- Represent pharmaceutical and life sciences clients on Public Readiness and Emergency Preparedness (PREP) Act issues
- Represent health exchange contractors and plans participating in exchanges
- Succeeded in securing interim Patient Safety Organization (PSO) certifications from the US Department of Health and Human Services for the Northern Metropolitan Patient Safety Institute and the Alliance for Patient Medication Safety

- Represented Sanofi Pasteur in successfully persuading the Centers for Medicare and Medicaid Services (CMS) to declare three outpatient drugs to be outside of coverage under the Medicaid drug rebate program
- Successfully defended four hospital systems against separate class actions brought on by uninsured plaintiffs challenging nonprofit hospitals' charges
- Defended major managed care insurer in a Racketeer Influenced and Corrupt Organizations (RICO) Act matter involving fraud, extortion and related claims in In Re: Managed Care MDL class action litigation; prevailed on summary judgment after multiple appeals
- Regularly counsel on the acquisitions and divestitures of hospitals
- Managed and guided the reorganization of a large academic medical center
- Provide general representation to physicians and physician groups, including on such matters as executive compensation
- Regularly defend medical device manufacturers and individuals accused of criminal FDA violations, including successful representation of approximately 30 employees in a criminal investigation of off-label marketing and other alleged violations of the Food Drug and Cosmetic Act in which none of our clients were prosecuted
- Represent pharmaceutical manufacturers, physicians and corporate health care providers accused of kickbacks and fraudulent Medicare/Medicaid billing.
- Counsel clients on structuring contracts with the federal government and maximizing reimbursements under these contracts

Our team has recently addressed cutting-edge topics involving:

- Stark and anti-kickback laws
- Government and legislative affairs
- Physician contracting
- Governmental investigations and fraud proceedings, including qui tam proceedings
- Mergers and acquisitions
- Medical staff peer reviews
- Privatization of health care facilities
- Medicare, Medicaid and managed-care issues
- Not-for-profit hospitals
- FDCA violations
- Health care exchanges
- Compliance reviews and risk assessments

When you turn to Dentons for help, you can trust that your matter is handled sensitively, professionally and responsibly by a team with the knowledge and passion to succeed.

Your Key Contacts

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