

Serving the Healthcare Industry





King & Spalding's healthcare industry practice has grown to encompass more than 260 professionals who serve the entire spectrum of healthcare providers, practitioners, investors, manufacturers, suppliers, vendors, educators, researchers, and inventors.

Our growth as a professional firm to the healthcare industry is attributable to our track record in achieving outcomes our clients value. We become partners with our clients in developing and executing complex transactions, litigation strategies, government reimbursement solutions, regulatory compliance initiatives, managed care contracting strategies, and efficiency/cost reduction measures. We understand our clients' business operations and shape our advice and counsel to the achievement of our clients' strategic objectives. Our clients tell us that we excel not only in efficiently delivering uncompromising quality, but also in making our clients' problems our own.

We participate directly in the industry ourselves, serving as trusted advisors, commentators on business trends, and advocates for the advancement of healthcare policy. Over the years, we have been fortunate to have some of the best and brightest talents in our field join us in this work.

Chambers USA has consistently ranked King & Spalding's Healthcare practice among the top 5 in the United States.

"Highly regarded for its work with an impressive array of clients, such as research institutes, medical manufacturers and investors. Offers high-quality representation in all areas of healthcare law."

CHAMBERS USA

Healthcare Litigation

Our healthcare litigators are trained to successfully litigate in state and federal court, in administrative proceedings, before arbitration panels, before juries, and in various appellate forums. Our deep understanding of federal and commercial payor reimbursement mechanisms provides unique insight into potential case strategies that inform our handling of False Claims Act (FCA) lawsuits, commercial managed care disputes, government reimbursement disputes and civil litigation.

FALSE CLAIMS ACT AND WHISTLEBLOWERS

Our lawyers have significant experience litigating allegations of healthcare fraud that present themselves in federal and state FCA cases. We are equally adept at pivoting between investigations and negotiations with government agencies and full-blown litigation of matters with whistleblower counsel – as the case may demand. Our understanding of healthcare operational and compliance processes has made our team particularly effective in negotiating and implementing corporate integrity agreements (CIA).

MEDICARE/MEDICAID REIMBURSEMENT LITIGATION

Our lawyers have handled reimbursement appeals of every type—including cost report payment disputes heard by the Provider Reimbursement Review Board, coverage disputes that proceed from the redetermination process through an Administrative Law Judge to the Medicare Appeals Board, and provider-status disputes that proceed to the Departmental Appeals Board—resulting in more than \$1 billion in payments to our clients. Our team includes the former head of Medicare reimbursement litigation at the Department of Health & Human Services (HHS) Office of General Counsel.

MANAGED CARE LITIGATION

We also represent provider clients in significant payor-provider disputes. We are market leaders in understanding a wide range of contracting strategies. Our experience with complex, specialized managed care legal issues like ERISA preemption, insurance regulation and antitrust compliance allows us to affect the payor-provider dynamic in a way that provides substantial benefit for our clients.

PRODUCT LIABILITY LITIGATION

The American Lawyer, *Law360*, *Chambers USA*, and *U.S. News & World Report* have all recognized our Product Liability practice as among the best in the United States. These recognitions stem from our work handling highly complex and—in many cases—“bet the company” products liability cases for healthcare clients in the pharmaceutical, medical device, medical service, consumer product and asbestos industries.

CLASS ACTIONS

U.S. News & World Report and *Best Lawyers* recently named King & Spalding “Law Firm of the Year” for Mass Tort/Class Action Defense, in addition to naming our healthcare practice in the top tier of U.S. firms. Our healthcare class action experience includes representation of several nonprofit hospital systems in Georgia and West Virginia in their defense of class action litigation brought on behalf of uninsured patients, successfully resolving all the Georgia cases on motions to dismiss or through voluntary dismissals.



Representative Healthcare Litigation Experience

- A hospital system in the favorable settlement of *qui tam* actions seeking more than \$100 million in damages in which the relator alleged upcoding, improper billing, and violations of the Stark Law and Anti-Kickback Statute.
- 700 hospitals in winning a global settlement of \$1.7 billion in administrative appeals and federal court litigation challenging annual wage index miscalculations affecting the standard payment rate applied to determine past, present and future Medicare payments for inpatient hospital services.
- A pharmaceutical manufacturer in cases brought by state Attorneys General alleging fraud, violation of consumer protection laws and state Medicaid laws, and unjust enrichment in the reporting of certain prices for prescription drugs.
- A coalition of some of the nation's largest disposable products suppliers in challenges to state laws seeking to restrict Medicaid beneficiaries' choice of eligible suppliers to a single source.
- A nationwide operator of diagnostic imaging facilities in the complete reversal of an \$11.1 million FCA judgment on appeal.
- A pharmaceutical manufacturer in litigation involving a leading antidepressant, including multi-district proceedings in California and individual suits throughout the country.
- A nursing home operator in successfully persuading the Department of Justice (DOJ) to dismiss an FCA case without the relator's consent, resulting in dismissal in favor of our client in a case that also included a private cause of action under the Controlled Substances Act alleging improper prescription of controlled substances to nursing home residents.
- A hospital in settling an FCA lawsuit in federal court brought by cardiologists formerly on the hospital's staff alleging violations of the Stark Law and Anti-Kickback Statute.

Regulatory Compliance, Operations and Advocacy

Our specialized healthcare industry knowledge allows us to understand and assess the risks our clients face and to develop strategies for managing those risks—whether we are advising clients on developing compliance programs, executing advocacy strategies, or providing guidance regarding ongoing compliance with the terms and conditions for operating pursuant to a corporate integrity agreement. Our team includes many members who have served in the government, providing us a strong perspective on the inner workings and objectives of the governmental and regulatory bodies with which we interact.

REGULATORY AND COMPLIANCE COUNSELING

We advise healthcare industry clients on all aspects of federal and state regulatory matters, including compliance with fraud and abuse laws, HIPAA regulations, as well as licensure, accreditation and certification requirements. We also counsel our clients regarding 340B drug discount program participation, conflict of interest disclosure and management, CIAs, consent orders and compliance with other state and federal standards and regulations.

CORPORATE COMPLIANCE PROGRAM AND RISK ASSESSMENTS

In addition to conducting corporate compliance program and risk assessments, we assist with the implementation and enhancement of compliance measures designed to target identified risk areas. We also help our clients to identify the need for and manage the process of internal and external audits and reviews and to develop disclosure strategies.

GOVERNMENT INVESTIGATIONS

Our government investigations team handles all varieties of criminal, civil and administrative healthcare investigations, with particular expertise in investigations and litigation under the FCA, including investigations involving Stark Law and Anti-Kickback Statute violations; Medicare and Medicaid overpayment investigations; and quality of care challenges. From high-profile criminal fraud and abuse matters to private, internal corporate compliance issues, our approach is uniquely tailored to each client and each set of facts.

MEDICARE/MEDICAID PAYMENT AND REGULATORY COUNSELING

We have years of experience in understanding both Medicare Part A and Part B and Medicaid reimbursement systems applicable to providers, suppliers and practitioners. Our team routinely counsels clients on a wide variety of payment issues, including cost-based, charge-based and prospective payment reimbursement systems; disproportionate share hospital payments; Graduate Medical Education (GME)/Indirect Medical Education (IME) reimbursement; electronic health records incentive payments; alternative payment models; and Medicare and Medicaid enrollment matters.

MEDICARE/MEDICAID AND OTHER GOVERNMENT CONTRACTOR AUDITS

We partner with healthcare providers to prepare for and manage government contractor audits and disputes involving Medicare and Medicaid Recovery Audit Contractors (RACs), Medicaid Integrity Contractors, Zone Program Integrity Contractors, Program Safeguard Contractors, Medicare Administrative Contractors, and Medicare Drug Integrity Contractors and others. Our lawyers recognize the critical importance of preparing for these government contractor audits and appeals and effectively responding to requests for information. We remain available to assist, but equally as important, we work to transition our expertise to our clients so they can self-handle the majority of lower-level appeals. We are also postured to assist with more complex, higher-level appeals before the Medicare Appeals Council and in federal district court.

LABOR AND EMPLOYMENT

Human resources are vitally important in healthcare, and we assist with all aspects of labor and employment law, ranging from preventive advice and training to class and collective action litigation under federal and state laws.

GOVERNMENT ADVOCACY AND PUBLIC POLICY

We use our healthcare industry expertise and long-standing relationships with the federal government to help clients effectively manage their relationships with key members of the House, Senate, U.S. Department of HHS, Centers for Medicare & Medicaid Services (CMS), Food & Drug Administration (FDA) and other executive branch agencies. The Government Advocacy & Public Policy practice, based in our Washington, D.C., office, is particularly familiar with handling congressional investigations and direct advocacy before Congress and executive agencies.

ENVIRONMENTAL, HEALTH AND SAFETY

Our Environmental Health and Safety (EHS) team understands the unique regulatory and enforcement challenges confronting healthcare organizations and includes lawyers with substantial experience in chemistry and engineering. We advise healthcare industry clients on pharmaceutical waste, air emissions and energy management issues. Our lawyers also develop and review the effectiveness of EHS management systems, including aligning them with The Joint Commission's accreditation standards. We also assist clients in responding to federal and state compliance and enforcement initiatives.

PROVIDER REPRESENTATION AND COUNSELING

We counsel providers of all sizes, spanning the entire care continuum from professional organizations to acute care hospitals and from home health providers to long-term care facilities. Our broad experience helps address needs in areas such as strategic planning, new service development, joint venturing, contracting, antitrust, risk management, physician recruitment, fraud and abuse compliance, and Medicare and Medicaid billing and reimbursement. We also excel in assisting our clients with operational matters such as medical staff credentialing and peer review, Medicare enrollment, facility licensure and certification, provider-based status, EMTALA, and clinical research.

Representative Healthcare Regulatory Compliance, Operations and Advocacy Experience

- Multiple national and regional healthcare systems and numerous individual hospitals in connection with government contractor audits and disputes, including Medicare and Medicaid RACs, Medicaid Integrity Contractors, Program Safeguard Contractors and Zone Program Integrity Contractors.
- Pharmaceutical and medical device companies in congressional investigations in both the House and Senate.
- Multiple healthcare organizations in matters under the Stark Law self-disclosure protocol.
- A hospital district in the development and implementation of a Medicaid supplemental payment/1115 Waiver program to provide enhanced Medicaid payments to hospitals and other providers.
- Numerous health systems on negotiating and complying with CIAs with the Department of Health and Human Services (HHS) and the Office of the Inspector General (OIG).
- A dental management company in connection with exclusion proceedings and investigations by the DOJ, the OIG, and a number of states.
- A pharmaceutical manufacturer in an investigation by the DOJ of its alleged off-label sales and marketing of an FDA-approved prescription drug.
- A Fortune 100 healthcare company in administrative proceedings before the Drug Enforcement Agency (DEA) and in related district and appellate court litigation, including obtaining a temporary restraining order against the DEA.
- A national drug toxicology laboratory in the defense of a \$31 plus million Medicare overpayment stemming from a Zone Program Integrity Contractor post-payment claim audit.
- The King & Spalding RAC Coalition, consisting of 15 major health systems across the country, in successfully lobbying Congress to reform the RAC process designed to reduce the burden of RAC audits on providers.

Health Information and Innovation

King & Spalding is at the forefront of global law firms providing legal services related to healthcare technology. Our broad and deep industry experience in the technology arena, together with our unparalleled experience in advising both life sciences and healthcare companies, enables us to partner with clients to their competitive advantage in the complex, fast-paced, and rapidly evolving world of health information and technology.

King & Spalding also represents a wide range of participants in the healthcare industry in the full range of HIPAA and other health information privacy and security compliance issues, including those applicable to HIPAA-covered entities, business associates, research organizations, research sponsors, and vendors of health informatics products.

HEALTH INFORMATION PRIVACY AND SECURITY


Our Health Information Privacy and Security team is part of the firm's broader Data, Privacy and Security practice, and we have considerable experience assisting covered entity and business associate clients in connection with their implementation of privacy and security policies and procedures. We also assist our clients with the investigation, management and reporting of security incidents and breaches involving protected health information at the state and federal levels.

HEALTH INFORMATION TECHNOLOGY AND ELECTRONIC HEALTH RECORDS

Our expertise in healthcare technology covers virtually all legal issues related to the utilization of technology in healthcare products and services. We assist clients in such endeavors as negotiating licensing agreements, responding to funding initiatives and participating in information exchanges.

TELEMEDICINE

Most states require commercial plans to cover telemedicine, and many states require parity from Medicaid, while government agencies, from the FDA to the Federal Trade Commission (FTC), oversee and consider the need for further regulation of telemedicine and telehealth. We develop compliance programming for private companies and providers to address these concerns and anticipate what is coming. We also assist telemedicine and telehealth providers with understanding the myriad of applicable state and federal laws within their programs and practices; developing web-and application-based processes and documentation; and creating policies, procedures and other programming necessary to provide compliant, reimbursable telemedicine and related services.



Representative Health Information and Innovation Experience

- A national system of substance abuse and mental health clinics in investigating and analyzing the risk of a stolen laptop that contained PHI on thousands of patients, including celebrities, and in handling required notices of breach, reports and filings with OCR and approximately 22 state Attorneys General.
- A party responsible for data security at a California hospital system with advice on the argument that ultimately prevailed on appeal in one of the largest class actions to date involving a health data breach, which resulted from the theft of an unencrypted computer containing data on more than 4 million patients.
- A hospital group purchasing organization and its 2,300 hospital members on electronic health records incentives and penalties under the HITECH Act passed as part of the American Recovery and Reinvestment Act of 2009.
- The second largest telehealth/telemedicine provider in the United States on regulatory, compliance and other legal issues throughout its development and growth into multiple organizations, including advising on all aspects of its operations and structures.
- A large publicly traded healthcare company in the development of a comprehensive Information Security Program governing the use and disclosure of the company's confidential information, including patient information subject to HIPAA and state health information privacy laws and personally identifiable information regulated under state laws.
- A medical device company on the transfer of personal data from its European offices to the United States including compliance with European data protection filing requirements and EU model contracts.
- Numerous clients in internal investigations concerning security incidents, including advice and recommendations regarding legal obligations and security improvements.
- Multiple clients in U.S. Department of HHS Office for Civil Rights HIPAA security audit and compliance investigations.

Healthcare Transactions

The transformation in treatment and payment models underway in healthcare today is impacting nearly every healthcare organization. Traditional ownership structures of healthcare entities are being challenged while new alignments and efficiencies are being conceived and implemented. Our team is experienced in these types of transformative transactions and the nuances that come along with the changing landscape. We also routinely advise and develop solutions for our clients in light of the healthcare legal and regulatory challenges presented in various financing structures.

M&A AND OTHER TRANSACTIONS

Our healthcare dealmakers guide our clients from the initial management and boardroom discussions to negotiating and closing mergers, acquisitions, joint ventures, joint operating agreements and other collaborations. We advise on all aspects of these transactions, including multistate regulatory approvals, legal risk assessments, tax structuring, antitrust analysis and public company and going-private issues.

PRIVATE EQUITY

Our healthcare private equity lawyers regularly represent private equity funds, private equity management groups and other institutional investors in transactions in the healthcare industry. We have a deep bench of lawyers representing healthcare industry clients in structuring, negotiating, and executing leveraged acquisitions and venture capital and growth financings, and in dispositions of investments through sales, public offerings and recapitalizations. Investors frequently engage us for our specialized due diligence examinations of target companies, including compliance history relating to Anti-Kickback, Stark, FDA, reimbursement and other laws.

FINANCE

Our Finance practice routinely represents lenders, investors, equity sponsors, issuers and borrowers in financings for companies in all sectors of the healthcare and pharmaceutical industries, including Medicare providers, medical equipment suppliers, healthcare technology companies, physician practice management companies and pharmaceutical companies. We structure, negotiate and conduct due diligence for acquisition financings, exit financing from bankruptcy, asset-based credit facilities and leveraged cash flow transactions, on both a syndicated and a single-lender basis.

TAX-EXEMPT BOND FINANCINGS

Our team is well-versed in the issues in structuring financings for healthcare groups made up of both nonprofit and for-profit entities, and we have broad knowledge regarding a range of bonds and financing structures, including variable rate bonds, commercial paper, derivative instruments used to hedge interest rate exposure, various types of credit or liquidity enhancement and other essential aspects of such transactions. We also represent healthcare institutions in investigations and examinations by the IRS and SEC related to tax-exempt bond financings and in connection with voluntary compliance applications.

FINANCIAL RESTRUCTURING

Our financial restructuring team works seamlessly with our healthcare reimbursement, finance, regulatory and transactional lawyers – bringing together innovative financial restructuring techniques with the deep healthcare industry knowledge that is invaluable in guiding the restructuring of companies in this field.

MANAGED CARE CONTRACTING

We are often involved in negotiating the language required to implement complex payment structures, including DRG-based case rates, bundled payments, outpatient surgery rates, transplant and other specialty services rates, and facility and professional capitation, to name only a few. Equally important are network participating provisions, particularly in tiered and narrow network agreements. Our background representing providers in hundreds of millions of dollars in disputes with payors over three decades has given us a unique perspective on provider contracting. It allows us to suggest terms that will minimize future disputes and administrative expenses associated with variances in expected reimbursement.



TAX

In addition to assisting new healthcare organizations in formation and application for tax-exempt status, we routinely advise established tax-exempt organizations on compliance with the complex tax laws governing them, including unrelated business taxable income issues, intermediate sanctions and the requirements of Internal Revenue Code Section 501(r). We also advise taxable and tax-exempt healthcare clients on the tax consequences of mergers, acquisitions, joint ventures and significant contracts.

REAL ESTATE

Our real estate specialists advise real estate businesses such as public and private investment and opportunity funds, investors, developers, REITs and lenders that invest in or finance healthcare real estate as well as healthcare providers that have real estate needs. We structure, negotiate and conduct due diligence for all types of healthcare real estate transactions, including forming healthcare private equity funds and REITs, acquiring hospital system assets, developing senior living facilities, acquiring or selling surgical centers, negotiating medical office joint ventures and structuring sale/leaseback of various facilities.

Representative Healthcare Transactions Experience

- A health system in the \$575 million acquisition of five hospitals and 26 clinics and treatment facilities, as well as a system-wide hospital revenue cycle services agreement.
- A private equity fund in acquisitions of three healthcare information technology companies with a total value of \$590 million.
- A healthcare financial services company in seven transactions totaling more than \$1 billion.
- A Catholic health system on the negotiation of a Joint Operating Company agreement with an academic medical center.
- Nonprofit health systems or underwriters of nonprofit health systems with the issuance of approximately \$4 billion of debt over 3 years.
- A Fortune 100 Global 100 healthcare services and information technology company on healthcare regulatory matters with respect to the formation of a joint venture with annual revenue of over \$3 billion.
- A statewide public employee retirement program in contract negotiations with its contracted health plans with a total annual healthcare spend for beneficiaries of over \$8 billion.

Specialized Healthcare Counseling

The size and diversity of our healthcare practice enable us to offer our clients advice in a number of specialized areas that require deep expertise in specific health law contexts.

ACADEMIC MEDICAL CENTERS

We have extensive experience working with Academic Medical Centers (AMC) on organizational, transactional and regulatory matters and in related litigation, including complex business transactions, Accountable Care Organization (ACO) development and other Affordable Care Act implementation matters, GME/IME affiliation agreements and payment issues, teaching physician billing and PATH audits, and obtaining favorable OIG advisory opinions.

ANTITRUST

Our leading healthcare antitrust lawyers, who include FTC and DOJ veterans, help clients gain clearance from applicable agencies for acquisitions and strategic transactions and affiliations; respond to government investigations; and successfully handle civil and criminal litigation. We also regularly provide counsel on antitrust aspects of managed care contract negotiations and terminations, messenger model networks, financial and clinical integration issues, and distribution, marketing and pricing practices.

CHILDREN'S HEALTH

Our attorneys who focus on children's health matters have specialties in reimbursement, compliance, government advocacy, clinical research, drug and device law, and intellectual property law. We have represented children's hospitals in regulatory and litigation matters involving the Children's Hospitals GME Program, including the first and only agency appeal regarding the allocation of funds under that program.

INTERNATIONAL HEALTHCARE

Our attorneys in Europe, the Middle East and the United States provide corporate structuring, health regulatory compliance and transactional support to clients involved in international healthcare transactions, service delivery and cross-border investments. They also assist in fund formation and financing of healthcare projects, provide Foreign Corrupt Practices Act guidance and represent these clients in international arbitration.

MANAGED HEALTHCARE

Our understanding of complex, specialized managed care legal issues – such as ERISA preemption, insurance regulation, and antitrust compliance – allows us to affect the payor-provider dynamic in a way that provides significant benefit for our clients. We assist in the design and formation of multi-provider networks, physician clinical integration models, ACO projects and provider-sponsored insurance entities.

CLINICAL RESEARCH COMPLIANCE

We have extensive experience advising manufacturers and providers on clinical research agreements, compliance readiness, coverage analyses, time and effort reporting, clinical research policies and procedures, reimbursement issues, and fraud and abuse compliance. King & Spalding is a member of the Clinical Trials Transformation Initiative, an FDA-initiated public-private partnership that identifies ways to enhance efficiency and compliance in the conduct of complex clinical trials.



Representative Specialized Healthcare Counseling Experience

- A state medical school in formation of a hospital joint operating company, physician clinically integrated network and academic affiliation with a large health system.
- One of the nation's leading cancer research and treatment centers on a technical assistance and consulting agreement for the creation of a radiation oncology treatment center in Istanbul, Turkey.
- A public health system and teaching hospital in the Southwest in restructuring its system-wide professional services arrangements in a multi-specialty physician practice and faculty group.
- AMC in recovering approximately \$16 million for all the academic years at issue in an administrative appeal of the denial of all Medicare funding for a new GME program.
- One of the country's largest AMC in successfully convincing the government to drop its FCA investigation of its Medicare outlier payments.
- An AMC in resolving a major investigation of its Institutional Review Board by the U.S. Office for Human Research Protection.
- A large public healthcare system in its formation of a hospital and physician joint venture with a competitor—combining over 3,000 physicians and several hospitals—and the successful clearance of the transaction by the FTC.
- The first partly foreign-owned hospital in Saudi Arabia on corporate, restructuring, labor, intellectual property and compliance matters.
- A public state university in the creation of a new medical school.
- A hospital group in restructuring its Abu Dhabi operations, resulting in its initial public offering on the London Stock Exchange.

In some jurisdictions, this may be considered “Attorney Advertising.” King & Spalding consists of King & Spalding LLP, a Georgia, U.S., limited liability entity, and affiliated limited liability entities in the U.S., England and Singapore.

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