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 investors.

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 ranked King & Spalding’s Healthcare practice Band 1 in the Nationwide category

“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 courts, 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 informs our handling of False Claims Act (FCA) lawsuits, commercial managed care disputes, government reimbursement disputes, and civil litigation.

FALSE CLAIMS ACT AND WHISTLEBLOWERS
We have particular expertise in defending healthcare providers and payors against FCA claims and have handled FCA litigation involving myriad issues, such as alleged Stark Law and Anti-Kickback Statute violations, quality of care and medical necessity issues, and billing issues. With one of the largest healthcare practices in the country, King & Spalding offers one of the broadest and deepest benches of lawyers, scientists, and consultants specializing in the representation of for-profit and nonprofit healthcare providers in healthcare-related matters. As a result, King & Spalding possesses an unusual combination of substantial healthcare expertise and experience handling high-stakes FCA cases, both during the investigation stage and in litigation. Additionally, our understanding of healthcare operational and compliance processes has made our team particularly effective in negotiating and implementing corporate integrity agreements (CIAs).

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
Our Product Liability team, which Law360 has named five times as Group of the Year, leverages knowledge of the complex science and technology behind today’s products to deliver litigation victories. These recognitions stem from our work handling highly complex and—in many cases—“bet the company” products liability cases. With over 175 lawyers around the world, we handle the most significant individual, multidistrict, and mass tort lawsuits and class actions for product manufacturers, including healthcare clients in the pharmaceutical, medical device, medical service, and consumer product industries.

CLASS ACTIONS
Our Class Action Defense practice is a nationwide leader. We have litigated class actions in virtually every major jurisdiction throughout the country. In the past seven years, we have represented clients in hundreds of class actions, the vast majority of which have been dismissed or effectively resolved at an early stage in the litigation and on terms favorable to our clients. Consistent with our clients’ interests in these cases, we typically push for early dismissal or resolution through aggressive motion practice. At the same time, we are uniquely experienced in and capable of trying these cases to conclusion. We are one of the few firms with actual experience trying class actions to verdict.
Representative Healthcare Litigation Experience

• Our argument and briefing resulted in a win for over 200 hospitals in a lawsuit challenging Medicare hospital rates under the “Two Midnight” Rule.

• Received a favorable decision from the PRRB on an issue of first impression regarding the meaning of “acute care” when applied to Medicaid adolescent psychiatric patients for purposes of calculating a hospital’s disproportionate share payment. The issue is worth tens of millions of dollars to our client and has important financial implications for other hospitals as well.

• Represent one of the largest hospital chains in the nation in virtually all of its Medicare reimbursement appeals before the PRRB. In the past two years alone, we have represented our client in multiple PRRB hearings on issues involving graduate medical education payments, disproportionate share payments, and reasonable cost reimbursement, collectively worth more than $11 million.

• Recently prevailed—with an award of attorneys’ fees—in an arbitration in which our client health system had over $26 million at stake against a vendor providing outsourced revenue cycle services.

• Successfully argued in the United States District Court that a federal whistleblower lawsuit, worth $200 million and alleging our client submitted false claims to the Medicare and Medicaid programs, was subject to dismissal under the public disclosure bar.

• Successfully resolved a dispute between a hospital system and a health plan, using statistical sampling in a confidential arbitration that involved thousands of unpaid and underpaid hospital and professional claims paid pursuant to a complex fee schedule, and that also involved downgrades of level of care and medical necessity denials for services provided to commercial, Medicare Advantage and Managed Medi-Cal members.

• Representing a hospital system in a confidential arbitration with a health plan regarding whether the health plan improperly leased its network of contracted providers to a self-insured health and welfare trust fund group plan.

• Successfully defended 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.

• Won three successive cases, at the summary judgment and motion-to-dismiss stages, for long-term-care pharmacy Omnicare, defending against FCA allegations by relator Fox Rx.

• Negotiated a favorable FCA settlement for a national hospital system involving 14 of its California hospitals concerning short-stay inpatient admission and upcoding allegations. In conjunction with this settlement, we were able to obtain the Department of Justice’s declination in another qui tam lawsuit that was pending in the Northern District of Texas, which the relator subsequently dismissed. We also negotiated a five-year CIA with the HHS Office of Inspector General.
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 (CIA).

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 and HIPAA regulations as well as licensure, accreditation and certification requirements. We also counsel our clients regarding 340B Drug Pricing 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 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 lawyers handle all varieties of criminal, civil and administrative healthcare investigations, with particular expertise in investigations and litigation under the FCA, including investigations involving alleged 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 record (EHR) 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 Auditors, Medicare Administrative Contractors, Quality Improvement Organizations, Zone Program Integrity Contractors, Unified Program Integrity Contractors, Medicaid Integrity Contractors, and Medicare Drug Integrity Contractors. 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 handle internally 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 Health & Human Services (HHS), Centers for Medicare & Medicaid Services (CMS), Food & Drug Administration (FDA) and other executive branch agencies. The Government Advocacy & Public Policy practice, which is 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 help clients respond 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, organ acquisition and transplantation programs, nursing and allied health programs, EMTALA compliance, and clinical research activities.

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 Recovery Audit Contractors (RACs), Medicaid Integrity Contractors, Program Safeguard Contractors and Zone Program Integrity Contractors.
- 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.
- Major health systems and academic medical centers to draft uncompensated care, financial assistance and collection policies to comply with requirements under the Medicare S-10 worksheet, Section 501(r) of the Internal Revenue Code, Medicare bad debt regulations and various state indigent care billing rules.
- Multiple hospital-based and independent clinical diagnostic laboratories on reimbursement and CLIA compliance issues.
- 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 HHS and the HHS 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.
- Major urban hospitals in navigating Medicare geographic reclassifications to “rural” status, leading to increases in IME reimbursement, reduced penalties in CMS innovation models and preferential treatment with the 340B Drug Pricing Program.
- A national drug toxicology laboratory in the defense of a $31 million plus Medicare overpayment stemming from a Zone Program Integrity Contractor post-payment claim audit.
Health Information and Innovation

King & Spalding is at the forefront of global law firms providing legal services relating to healthcare technology. Our unparalleled experience advising life sciences, healthcare and technology 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 handles a broad range of HIPAA and other privacy- and security-related matters for a variety of organizations, including providers and other covered entities, business associates, research organizations, research sponsors, telehealth management services organizations (MSOs) 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. We regularly provide our clients with the full gamut of related services, from privacy and security risk assessments through compliance program development and day-to-day operations advice, including development and implementation of privacy and security policies and procedures and training. We also work with our clients in performing investigations; evaluating, managing and mitigating risk; assessing and advising on potential security incidents and breaches; and, where necessary, reporting breaches involving protected health information at state and federal levels.

HEALTH INFORMATION TECHNOLOGY AND EHRS

Our expertise in healthcare technology covers virtually all legal issues related to the utilization of technology in healthcare products and services, including EHRs, clearinghouse and warehousing functions, and data ownership. Our work has included negotiating licensing and other agreements, assessing compliance and developing compliance programs, responding to funding initiatives, and participating in information exchanges.

TELEMEDICINE/TELEHEALTH

Most states require commercial health plans to cover telemedicine/telehealth, as defined in each state, and almost all require that Medicaid plans cover prescribed telemedicine services. Government agencies, from the FDA to the Federal Trade Commission (FTC), oversee and consider the need for further regulation of telemedicine and telehealth. We offer advice daily to telemedicine/telehealth providers, MSOs and related entities; develop their compliance programming; and work with them to anticipate and prepare for what is coming. Specifically, we help our clients understand the myriad applicable state and federal laws and practice standards, trends and public policy concerns; develop web- and application-based processes, consent and authorization forms, and other online documentation, including Terms of Use, Privacy Notices and Notices of Privacy Practices where HIPAA applies; draft and negotiate contracts between and among providers and telehealth entities; create business structures, policies, procedures and other programming as necessary to ensure compliance with state and federal law; and help develop billing programs for federal, state and commercial reimbursement of telemedicine and telehealth 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 EHR 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 the HHS’s Office for Civil Rights HIPAA security audit and compliance investigations.
Healthcare Transactions

Continued regulatory uncertainty and cost pressures are driving an unprecedented rate of change in the healthcare industry. 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, divestures and corporate restructurings, joint ventures, joint operating agreements, and other collaborations. We advise on all aspects of these transactions, including state and federal regulatory approvals, legal risk assessments, nonprofit and for-profit 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, FCA, 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 and dental 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.

DISTRESSED PROVIDER ACQUISITIONS
Many healthcare providers, particularly rural and exurban hospitals, are facing significant financial challenges. Our lawyers have deep experience advising clients considering the acquisition of financially distressed hospitals and other healthcare providers. We have assisted clients with acquisitions and sales under Section 363 of the Bankruptcy Code.

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 the sale/leaseback of various facilities.

Representative Healthcare Transactions Experience

Our Firm’s Healthcare Transactions lawyers have handled the following matters:

• An investor-owned hospital system in a $750 million sale of all hospitals in a major U.S. metropolitan area.

• A publicly traded payment technology services company in its $700 million acquisition of an EMR company.

• A regional nonprofit healthcare system in its acquisition of five hospitals.

• A prison healthcare services company in a $250 million sale to a publicly traded insurance company.

• An academic medical center in a proposed business venture valued at $600 million with a hospital operating company to form a new 10-hospital health system.

• 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.

• An academic health system in its restructuring and creation of an independent entity to acquire its healthcare enterprise, and related financing thereof, in a transaction worth over $1 billion.

• The creation of a multibillion-dollar health system by joint operating agreement, and the subsequent acquisition of several hospitals by the health system.

• A university in the purchase of a hospital from a for-profit health system, and the creation and simultaneous contribution of the hospital to a newly formed regional health system joint venture with a community health system.

• Represent investor-owned hospital system in the sale of its Medicare Advantage plan.

• Nonprofit health systems or underwriters of nonprofit health systems with the issuance of approximately $4 billion of debt over three years.

• Represented multiple physician groups in various specialties in sale to private equity firms and publicly traded physician staffing companies.

• 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 (AMCs) 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 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.

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. We also regularly represent providers in negotiation of managed care agreements with third-party payors and in disputes arising from those significant relationships.

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 the formation of a hospital joint operating company, a physician clinically integrated network and an 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 multispecialty physician practice and faculty group.

- An 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.

- A nationally renowned children’s health system in the establishment and management of its network of off-campus provider-based departments.

- 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 state university in the creation of a new medical school and subsequent litigation involving local funding designated for the support and startup of the school.