

→ Healthcare

Sheppard Mullin's healthcare practice is the fastest growing – and one of the largest – multisector healthcare law practices in the U.S. With more than 230 lawyers, *Law360* repeatedly ranks us as U.S. Healthcare Practice Group of the Year.

Partnering closely with our clients, we provide strategic business solutions tailored to their business goals, challenges, and legal service needs. We offer pragmatic, creative solutions while drawing on our holistic industry perspective and legal prowess on transactional and regulatory issues and litigation-readiness. Our end-to-end capabilities encompass the right resources to help clients meet their legal and business objectives.

Clients

Our Healthcare team serves a wide array of clients across and tangential to the healthcare industry, including:

- Health Plans, Insurance Companies and Risk-Bearing Organizations
- Hospital Systems – Academic, Nonprofit, Religious and For-Profit
- Physicians and Dental Practices
- IPA, CIN and ACO Networks
- Digital Health, Telehealth, Healthcare Information Technology, Artificial Intelligence
- Healthcare Facilities, ASCs, Urgent Care and Other Clinics
- Private Equity and Hedge Funds and their Portfolio Companies
- ASCs, Home Health, Hospice, Labs, Imaging and other Ancillary Services Providers
- Post-Acute Care Providers
- Healthcare Finance Companies (Banks and Non-Bank Lenders)
- International Healthcare Entities and Investors
- Retail Pharmacy
- Specialty Pharmacy, Pharmacy Benefit Management, Pharmaceutical Manufacturers, Drug Discovery and Clinical Trial Companies
- Start-Ups and Early-Stage Healthcare Businesses
- Management Services and Revenue Cycle Management Organizations
- Veterinary/Animal Health Providers and Investors

Services

Our Healthcare team is full service, with deep experience in the following areas:

Mergers, Acquisitions and Joint Ventures

Named as a **Top 10 Healthcare Merger & Acquisition Law Firm** by *U.S. Healthcare M&A News*, Sheppard Mullin has one of the strongest national healthcare transactional practices in the country. We represent the full spectrum of healthcare industry participants in a broad variety of financial, structural and traditional corporate law matters, both large and middle-market, including:

- Mergers and acquisitions
- Private equity recapitalizations
- Joint ventures and strategic alliances
- Vertical integration transactions
- Corporate restructuring

We are valued for our broad and deep experience in advising healthcare organizations in connection with sophisticated, complex and innovative transactions. We understand the challenges and opportunities faced by our clients, and offer strategic, actionable solutions that help our clients achieve business objectives, protect and expand their business interests, and promote high quality and cost-effective patient care.

Compliance – Fraud and Abuse

Healthcare clients value our counsel in their regulatory compliance and enforcement issues. We routinely advise on physician self-referral laws, fraud and abuse laws, corporate practice of medicine and fee-splitting prohibitions, HIPAA privacy, charitable trust law, private inurement, private benefit and excess benefit restrictions, antitrust, licensure, accreditation, Medicare and Medicaid reimbursement, certificate of need/certificate of exemption laws and medical staff bylaws issues.

We serve as legal counsel to a wide variety of healthcare organizations involved in the delivery and financing of healthcare. Our advice helps clients navigate a multitude of regulatory issues associated with mergers and acquisitions, joint ventures, physician recruitment, acquisition of physician practices, physician contracts, physician practice management arrangements, governmental investigations and audits, whistleblower suits, Medicare and Medicaid coverage and reimbursement requirements, attorney general investigations, corporate governance/fiduciary duty issues, corporate compliance matters and medical staff disputes.

Sheppard Mullin provides comprehensive, insightful and cost-effective legal services to healthcare clients. From providing sophisticated advice to develop a business model that clears regulatory hurdles, defending an enforcement action or responding to a regulatory challenge, we assist in the following areas:

- Develop and implement healthcare regulatory compliance programs (including programs consistent with the OIG's Model Compliance Program Guidance for Pharmaceutical Manufacturers) designed to identify and mitigate life sciences-related regulatory risks in:
 - provider relations (including consulting agreements and speaking contracts)
 - pricing and marketing practices (including off-label marketing)
 - Medicare and other governmental program participation conditions and standards
 - Medicare Part D

- the Sunshine Act
- Conduct internal audits and investigations relating to compliance with myriad statutory and regulatory requirements including those related to:
 - the federal Antikickback Statute, Stark Laws, and corresponding state and federal laws that impact manufacturer/physician relationships
 - (ii) the Medicaid Drug Rebate Program
 - the 340B Drug Pricing Program
 - FDA rules and regulations
- Develop and conduct legal update and compliance seminars for boards of directors, officers, sales and marketing personnel, and administrative and clinical staff of national and regional diagnostic and therapeutic service providers covering various current compliance issues impacting provider clinical and business operations. Such issues have included:
 - Fraud and abuse and physician self-referral laws (e.g., Stark) and their application to physician interactions
 - HIPAA and HITECH and state-specific confidentiality and security laws
 - PhRMA and AdvaMed Codes
 - Sunshine Act requirements
 - Laws and policies relating to the Medicare reimbursement of healthcare provider and supplier services
- Provide HIPAA advice and compliance representation including the development and implementation of HIPAA compliance plans including the preparation and revision of privacy and security-related policies and procedures and business associate agreements
- Advise clients regarding the development and implementation of FCA and *qui tam* relator (whistleblower) risk mitigation strategies and programs
- Advise clients on disclosure and reporting obligations and strategies under the various federal and state false claims laws
- Leverage our hospital regulatory and compliance expertise to guide hospitals in:
 - Government healthcare program participation and reimbursements
 - Provider and payor licensing, certification and accreditation
 - Daily interactions with the healthcare-related federal governmental agencies (e.g., CMS, FDA, DEA, DHS) and New York state governmental agencies (e.g., Department of Health, Office of Medicaid Inspector General, Office for People with Developmental Disabilities)
- Our regulatory compliance attorneys assist clients in evaluating and structuring transactions or relationships to comply with the Stark Law, fraud and abuse laws, anti-kickback and fee splitting laws, Medicare billing compliance and the pertinent tax exemptions.

Commercial Litigation

Our healthcare litigation team protects the interests of our clients in commercial litigation and civil disputes, internal investigations and enforcement actions. Deep knowledge of the healthcare industry not only sets us apart, but it allows us to be effective advocates for our clients. The business needs of our clients and the

healthcare regulatory environment shape all aspects of our dispute management strategy, from possible out-of-court resolution of disputes all the way through trial. Our litigators possess exceptional trial and appellate skills, and regularly litigate in state and federal courts at all levels and venues across the country. Our team consists of over 250 seasoned trial and appellate lawyers that represent clients across the healthcare industry.

In addition to appearing in state and federal courts, we have significant experience appearing before various arbitral forums such as the American Arbitration Association (AAA), Judicial Arbitration and Mediation Services (JAMS) and the International Chamber of Commerce (ICC), representing healthcare entities through evidentiary hearings, state and federal court award confirmations and enforcements of judgment.

We bring and defend a broad base of claims and issues, including:

- Disputes arising from mergers, acquisitions and dispositions
- Federal Trade Commission and state attorney general antitrust enforcement actions
- Defense of False Claims Act and fraud and abuse claims
- Corporate governance and control
- Challenges involving contracts and reimbursement, including administrative appeals
- Class actions
- Bankruptcy of hospitals as creditors
- White collar and healthcare business crimes defense
- Employment, including wrongful termination, sexual harassment and class actions
- Enforcing restrictive covenants
- Fiduciary duty litigation
- Managed Care reimbursement and risk fund disputes
- Product liability and mass tort claims
- Real estate litigation, including planning, zoning and environmental disputes
- Telephone Consumer Protection Act violations
- Trade secret, patent and intellectual property disputes
- Union representation in litigation, arbitration and contract negotiation
- ACA § 1557 discrimination claims

False Claims Act Litigation

Sheppard Mullin's attorneys are among the nation's leading specialists with respect to healthcare False Claims Act cases, including those pertaining to kickbacks, up-coding services, services not rendered, ghost patients, bundling and unbundling, lack of medical necessity, false certification, research grant fraud, improper financial interests and referrals (including the Stark Law), inflating cost reports, inferior quality of care, red-lining, Medicare Part D fraud and related *qui tam* whistleblower actions. Our team includes former federal and state prosecutors and government attorneys, and health law practitioners. We have handled over 100 False Claims Act cases – from early investigation and resolution to complete defense verdicts at trial.

Our trial experience enables us to anticipate and shape the course of an investigation, putting our client in the best position to resolve it satisfactorily whether by settlement or trial defense.

After listening to our clients to understand their business needs and plans as well as their operational resources and constraints we've obtained declinations as well as defense verdicts in civil and criminal cases arising from alleged violations of the complex regulatory schemes our clients must navigate. Our clear guidance and practical advice allows them to manage the investigation or litigation in a manner that fits with rather than disrupts the broader framework of their objectives, priorities and resources.

Appeals, Disputes and Protests Involving Governmental Agencies

At Sheppard Mullin, we are committed to protecting our clients' interests and facilitating their continued growth within the dynamic and heavily regulated healthcare environment. We offer seasoned expertise in managing appeals, disputes and protests involving government agencies. Our formidable track record is rooted in years of direct engagement in these areas of practice, representing a diverse group of healthcare entities with various complexities and contexts. We have a proven history of successfully navigating our clients through the intricate legal landscape, involving numerous federal, state and local health authorities. Our focus is on addressing the unique legal challenges faced by our clients and resolving disputes efficiently and effectively, ensuring compliance with the evolving healthcare regulations.

Value-Based and Global Risk Arrangements

Today's U.S. healthcare market is seeing rapid change, and Sheppard Mullin is leading an unprecedented level of the most innovative transactions addressing the current trends of an accelerated movement to risk-based and value-based reimbursement structures; tremendous growth in the acquisition and launching of Medicare Advantage health plans and their acquisitions; and a national movement towards value-based contracting between payors and providers, with opportunity for greater reimbursement to providers if they create value for payors and members by increasing quality and reducing costs.

We represent most of the leading companies involved in implementing healthcare reform through coordinated care and population health management initiatives. We also regularly represent physician organizations in innovative transactions.

HIPAA, Data Privacy, and Cybersecurity

Health Information Privacy

We advise clients on the complex framework of privacy and security laws that regulate health information and impact data assets. Providers, patients, and health and wellness companies value our practical and sophisticated counsel in this area of growing concern. Our in-depth guidance includes advising on the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act ("HITECH"), 42 CFR Part 2 regulations ("Part 2"), the Genetic Information Nondiscrimination Act ("GINA"), the Biometric Information Privacy Act ("BIPA"), and other state and federal laws impacting health information and sensitive areas, all of which continue to evolve. Specifically, we regularly counsel some of the world's largest and most respected health systems, health plans, contract research organizations, pharmaceutical companies and technology companies on:

- HIPAA architecture and data flow structuring
- HIPAA and state data incident response, including governmental investigations
- Red Team review of public asset risks and table top breach assessments
- Data privacy compliance program development and review, including policy and procedures and manager and workforce training
- Data collaborations, including Data Access and Use Agreements and modernizing Business Associate Agreements
- Data as an asset programming and health information technology license agreements
- Tracking technology use
- Accessing and use of sensitive information
- Distinguishing consumer data and health information
- Applicability and compliance of state health information laws, such as California's Confidentiality of Medical Information Act ("CMIA"), Washington's My Health, My Data Act ("MHMDA"), and laws protecting sensitive health information, such as behavioral and reproductive health, substance abuse, and minor patients' rights
- Legal issues and risk mitigation strategies relating to artificial intelligence ("AI") and derivative data rights

Data Privacy and Security

Sheppard Mullin's award-winning data privacy and security team represents some of the largest and most respected companies across the global healthcare industry spectrum. We assist established and start-up innovators in healthcare businesses in assessing their current systems and vulnerabilities and identifying the laws and regulations that apply.

Navigating the web of privacy and security laws and regulations that often do not reconcile is a daunting task requiring experienced, knowledgeable, and practical legal counsel with a thorough understanding of data privacy and security laws and regulations as well as ethical and business considerations. Our healthcare data privacy and security attorneys include a former Deputy General Counsel at the United States Department of Homeland Security, a former attorney and investigator at the U.S. Department of Health and Human Services/ Office for Civil Rights, and a lawyer who literally wrote the book on data breach. Our team also includes a former FBI Special Agent and investigations specialists, award-winning privacy class action litigation practitioners, and leading EU-based data protection experts. Many of our team members are CIPP-US and CIPP-EU certified by the IAPP.

We advise clients on how to permissibly extract value from the data they collect, while identifying and addressing regulatory compliance requirements and ensuring that data is appropriately protected. Our attorneys have experience responding to high-profile data breaches, including state-sponsored attacks, and the regulatory investigations and litigation that often follow such incidents, including class actions. We also provide proactive and strategic counsel to help companies understand emerging developments in this rapidly changing area of law, particularly with cross-border collection and international data transfers including General Protection Data Regulation ("GDPR") compliance.

What We Do

- Counsel clients on managing data as an asset
- Establish data access and sharing programs, including preparing patient authorizations and notices
- Draft and review terms of use and privacy policies for health applications and websites
- Counsel clients on web-tracking risk and mitigation and use of novel technology
- Provide management, vendor and workforce compliance training
- Assist and advise clients in HITRUST certification and/or healthcare industry ISACs
- Advise on compliance with PCI-DSS, NIST, and other security standards
- Assist clients in achieving risk analyses, forensic reviews and auditing standards
- Draft and review contractual arrangements, such as Business Associate Agreements (“BAAs”), Data Access and Use Agreements, Contractor/Vendor Agreements and Payor Agreements
- Draft protective indemnification and contractual clauses related to data protections
- Prepare for and defend against governmental audits and investigations and private lawsuits and class actions
- Assist in compliance with applicable breach notification laws
- Conduct privacy and security diligence related to mergers, acquisitions, divestitures and other transactions and investments
- Counsel on legal issues related to AI and derivative data rights
- Advise on the legalities and risks of data transfers, including cross-border transfers
- Guide and negotiate cyber liability insurance coverage
- Advise on the Children’s Online Privacy Protection Act (“COPPA”)

Healthcare Real Estate and Finance

Sheppard Mullin’s healthcare real estate lawyers have a deep understanding of the complex regulatory issues that arise in healthcare real estate transactions and operations, including the Stark Law, Anti-Kickback Statute, co-location rules, and other federal and state healthcare regulations. Our Healthcare Real Estate team provides strategic counsel to health systems, providers and investors regarding regulatorily-compliant vehicles, such as joint ventures and other syndications, to monetize assets, maximize returns and provide quality patient care. Our team takes a business-minded, results-oriented approach that delivers market returns on investment, as well as a return on mission. We also counsel on compliance with tax matters, nonprofit corporation and canon law, and other ethical considerations.

Services include:

- Strategic planning, growth initiatives and value creation
- Mergers, acquisitions, dispositions, joint ventures and sale/leaseback transactions
- Healthcare facility leasing
- Stark law, Anti-Kickback Statute, co-location rules, fraud and abuse, reimbursement and antitrust
- Tax structuring and tax-exempt finance

- Healthcare finance
- Construction, land use and planning
- Title and survey, zoning and environmental review
- Operational matters and regulatory support
- Regulatory, leasing and other real estate disputes and litigation
- Non-profit finance

FDA

Our attorneys represent companies across an array of industries, from digital health and medtech to pharmaceutical, biologics, medical devices, dietary supplements, and cosmetics, on matters spanning the total product lifecycle, from concept to commercialization. We bring an innovative approach to resolving complex regulatory issues that complements our client's cutting-edge technologies and novel products.

Our work begins in the planning and research and development phases and includes counseling on strategies for product positioning, review of novel ingredients and technology, the conduct of clinical trials, and market and patent exclusivity options. As part of the product development and approval phase, we assist clients in preparing and submitting marketing applications, help facilitate meetings with FDA and other international regulators, and assist in preparing for pre-approval inspections. We also partner with clients to handle and resolve post-marketing issues, such as product safety issues, including adverse event reporting and recalls, import-export issues, obtaining supplemental approvals, responding to formal and informal agency enforcement actions, and all aspects of marketing, including, labeling, advertising and promotion issues. Our team also handles complicated legal and regulatory aspects of inspections and audits, including representing clients before the FDA and U.S. DOJ, conducting cGMP and QSR audits and data integrity reviews, and assisting clients in responding to agency enforcement actions, including 483s, warning letters and investigations.

Our attorneys also have extensive experience conducting regulatory compliance due diligence audits of potential acquisition targets and negotiating licensing, supply and distribution agreements.

Digital Health and Telemedicine

Sheppard Mullin is at the forefront in advising healthcare innovators on matters related to digital health technology, along with their emerging regulatory and legal implications. We leverage our multidisciplinary team with deep experience in cutting-edge digital health technologies, helping our clients bring next generation innovations to market, including, artificial intelligence (AI), telehealth and telemedicine platforms, blockchain, augmented reality (AR), virtual reality (VR), wearables, software and mobile health applications, digital therapeutics, remote patient monitoring, electronic health record platforms, value-based care and personalized medicine.

Our unique perspective and understanding of the operational and competitive issues health technology clients face helps position them to prosper in this rapidly changing landscape. We tackle the entire lifecycle of digital health issues across key disciplines such as healthcare regulatory, FDA, cybersecurity and data privacy, health technology, intellectual property, healthcare M&A and corporate structure strategy.

Artificial Intelligence, Machine Learning, Information Technology

Sheppard Mullin has extensive experience navigating the legal risks and challenges of integrating AI and other novel healthcare technologies. Understanding the wealth of current opportunities surrounding AI, we support clients as they navigate a range of ever-evolving considerations around its use, including digital health and telehealth regulations, data privacy, data as an asset strategies, the corporate practice of medicine limitations, licensing issues, intellectual property rights, ethical considerations and protecting against potential healthcare liabilities.

Our full service platform for AI in healthcare covers regulatory, commercial and transactional matters, such as:

- FDA approval pathway for AI as a medical device
- Reimbursement and the False Claims Act
- Privacy, data security, HIPAA and state regulations on data access and use
- Anti-kickback Statute, the Stark Law, and related fraud and abuse considerations
- Instituting compliance safeguards to address and contain risks presented by AI
- Assessing and addressing legal risk
- Counseling digital healthcare providers and telehealth providers
- State and federal regulations addressing the practice of medicine, fee splitting, etc.)
- Technology licensing
- Intellectual property strategy and protection
- IT contract negotiations
- Vendor negotiations and outsourcing
- Financing
- Deal structuring and negotiations, such as M&A, joint ventures and strategic collaborations related to healthcare transactions
- Due diligence expertise specifically tailored to each sub-industry
- Integrating AI functionality into operations
- Working with emerging healthcare technology companies and investors

Provider Alignment Transactions

Sheppard Mullin is the preferred law firm for health plans, hospital systems and providers considering convergence transactions that result in successful provider alignment. In addition to traditional payer contracts, we structure the full range of value-based and risk-based reimbursement arrangements, including full risk and global risk agreements. We have worked with many clients on transitioning to risk-based reimbursement and implementing effective alignment strategies.

We work with leading national compensation consultants to formulate innovative and effective compensation approaches. We are experienced with traditional, shared savings, incentive based and capitated/percent of premium contracting arrangements and can share the best practices we have learned from multiple engagements, as well as structures to avoid. Few other healthcare law firms have our multisector practice,

which allows us to take the knowledge and experience we gain in one sector and apply it to another.

Health Plan Strategic Transactions, Licensing, Contracting and Compliance

Sheppard Mullin's work on some of the largest and most complex industry transactions of publicly traded and privately-held health plans includes multiple multibillion health plan and provider transactions. This work often includes helping our clients obtain licensure under state HMO and insurance laws including the California Knox-Keene Health Care Service Plan Act, contracts under the Medicare Advantage, Medicare Prescription Drug and state Medicaid managed care programs, and compliance with Medicare Advantage, Medicare Part D, Medicaid managed care, Federal Employees Health Benefits Program and Marketplace requirements. When needed, we also support them in appealing agency decisions and resolving disputes. Our lawyers regularly provide education and training to health plan administration teams, in-house counsel, and compliance staff on an array of issues including fraud and abuse, risk adjustment, medical loss ratio and other compliance matters.

- Represent leading HMOs and insurance companies on projects such as mergers and acquisitions, vendor and provider contracting, joint ventures, risk-based arrangements, physician alignment and population health management initiatives
- Our Healthcare Antitrust practice has been actively involved in multiple negotiations with federal and state antitrust regulators on some of the most complex and heavily scrutinized transactions. We work at the forefront of structuring innovative relationships for both providers and payors undertaking significant transactions, including mergers, joint ventures, intellectual property licenses, and a variety of other affiliations and collaborations
- Advise health plans that are federal healthcare program contractors on a broad array of issues related to program participation including application submissions, bidding and rating requirements, benefit design, provider contracting and compensation issues including the federal Physician Incentive Plan regulations, medical loss ratio requirements, risk adjustment payment issues, employer group waiver plans, marketing, internal investigations, and program and inspector general audits
- Provide strategic advice and counseling to health plans in response to state and federal agency investigations, such as market conduct exams, medical loss ratio audits, Mental Health Parity and Addiction Equity Act compliance and ACA Section 1557 discrimination complaints
- Represent health plans in litigation, administrative proceedings and appeals such as denials of initial and service area expansion applications and the imposition of civil money penalties by the Centers for Medicare & Medicaid Services (CMS)
- Active in the development and implementation of health plan vertical integration strategies for physician groups and networks with plans that are designed to lower health plan provider-related costs, increase patient care quality and secure member access to providers by stabilizing the plan's provider network
- Represent full-service and specialty health plans (including dental and vision plans) in a wide variety of licensing, regulatory, transactional and litigation matters, such as L.A. Care Health Plan, one of the largest public health plans in the country serving low-income and vulnerable populations in Los Angeles County
- Counsel health plans in dealing with solvency issues involving their provider networks, working with multiple companies that provide support and outsourcing solutions to health plans, including utilization review, sales and marketing, and independent review organizations

Antitrust

Antitrust Transactions

Our healthcare antitrust practice helps our clients navigate investigations and enforcement actions in some of the most complex and heavily scrutinized transactions in the industry. We work closely to identify potential risks and develop strategies to navigate the enforcement landscape:

- Structure innovative relationships for health systems, hospitals, academic medical centers and providers. Clients pursue their business and clinical objectives while minimizing antitrust risks in significant transactions including mergers, joint ventures, intellectual property licenses, and in a variety of other affiliations and collaborations.
- When a corporate transaction, competitive collaboration or innovative affiliation requires state or federal review or garners the attention of antitrust enforcement authorities, clients rely on our deep experience advocating for clearance before state and federal antitrust authorities.

While the rise of state antitrust enforcement regimes in the healthcare industry is not new, with states implementing or considering new laws and regulations requiring additional approvals for healthcare transactions. These emerging state-level reporting regimes are tracked in Sheppard Mullin's interactive map available here, which identifies states with reporting regimes and provide a high-level indication of the types of requirements that may be imposed on healthcare transactions captured by the regimes.

Defense of Antitrust Investigations and Federal, State and Private Party Litigation

Our Antitrust and Competition group regularly works on numerous matters involving the DOJ, FTC and state attorneys general. We also counsel clients and handle litigation involving the Sherman, Clayton, Federal Trade Commission and Robinson-Patman acts, as well as state antitrust statutes and regulations. Our team regularly:

- Defends healthcare providers in private litigation and class actions.
- Represents clients facing civil and criminal investigations by the FTC, the Antitrust Division of the DOJ, and state attorneys general arising out of M&A activity and in conduct matters.

Antitrust Counseling & Compliance

Our full-service healthcare antitrust team works hand-in-hand with in-house teams on a daily basis to:

- Develop robust antitrust compliance programs to identify and mitigate potential risks.
- Form risk-bearing entities, establish integrated delivery systems, expand vertically into the payer or technology space and implement shared-services agreements.
- Provide antitrust advice relating to clinically integrated networks (CINs), value-based and outcomes-based reimbursement models, risk-based contracting, accountable care organizations (ACOs), Medicare bundled payment initiatives and price-transparency initiatives.

Medicare Advantage, Medicare Prescription Drug, Medicaid Managed Care and ACA Marketplace Operations and Compliance

We advise health plans that contract with federal or state agencies under federal healthcare programs, including Medicare Advantage, Medicare Part D, and Medicaid managed care, as well as the ACA Marketplace and the Federal Employees Health Benefits Program. We assist health plans in applying for initial contracts, filing rate and benefit bid submissions, medical loss ratio, risk adjustment, changes of ownership and appealing agency adverse decisions.

HCC-RAF Contracting Programs and Provider Incentive Programs

For many Medicare Advantage providers and plans, Medicare's risk adjustment reimbursement methodology (the Medicare Hierarchical Condition Category (HCC) – Risk Adjustment Factor (RAF) program) is becoming of increasing and critical importance to success. We represent both plans and providers on all aspects of their risk adjustment programs:

- Defending providers in federal HCC-RAF investigations
- Structuring physician incentive programs (e.g., physician stratification programs) and education programs for risk adjustment activities
- Counselling on compliance issues and audit issues
- Assisting with rolling out or assessing HCC-RAF programs for medical groups, IPAs, risk bearing organizations, and Medicare Advantage plans

Managing Enforcement Risks and Compliance

Given the growing enforcement efforts from federal authorities, it is imperative to manage potential enforcement and compliance risks. Our substantial experience advising clients on compliance includes conducting internal investigations, supervising coding reviews by consultants, and, for providers, executing voluntary disclosures and refunds to payors when legally required on HCC-RAF issues. Given our real world experience with both federal enforcement efforts and with effective HCC-RAF coding compliance strategies, we assist providers and plans in pursuing risk management strategies while allowing for the compliant capturing of diagnosis codes to properly generate revenue that is presently being left behind.

Representing Plans

Medicare uses HCC-RAF scores to determine the complexity of a given beneficiary's medical condition. With higher payments made by Medicare for more complex (*i.e.*, sicker patients), Medicare Advantage plans that have robust programs in place to ensure accurate HCC-RAF coding can see increases in top-line revenue for their more complex beneficiaries. We have experience counseling plans on the various components of HCC-RAF compliance and performance. In addition to regulatory compliance and payment issues, we recognize risk adjustment programs are also vital to a plan's analysis of the overall risk present in its member/enrollee pools and ensuring sufficient diversity for financial success.

Representation of Risk Bearing Provider Organizations

We work with risk bearing organizations to stratify the pool of physicians and other healthcare providers in their network. These tools enable providers to maximize performance and reward high performing doctors, as well as identify doctors who are struggling and may need additional training, assistance and support to succeed.

Tax and Employee Benefits

Tax

A core component of Sheppard Mullin's tax group is advising on both national and international mergers and acquisitions, including for all healthcare transactions. The group assists in analyzing and structuring the form of the transaction, preparing legal opinions addressing the tax consequences of the transaction, and assists in preparing SEC materials and proxy statements. Our attorneys advise on all types of sales, acquisitions and reorganizations, including taxable and tax free:

- Acquisitions, sales and mergers
- Forward and reverse triangular mergers
- Asset-for-stock acquisitions
- Recapitalizations and consolidations
- Holding company formations and spin offs
- Stock-for-stock reorganizations
- Roll ups
- Management equity rollovers

Our tax partners actively work on healthcare merger and acquisition matters, with involving our tax and benefits attorneys as necessary.

ERISA and Employee Healthcare Benefits

Our ERISA and Employee Healthcare Benefits team understands the organizational, regulatory and corporate structuring complexities facing clients in the healthcare service industry, and the impact those complexities have on employee benefits. Our team members have extensive experience advising healthcare service industry employers on ERISA's controlled group/affiliated service group requirements that impact employee benefit plans. We also help them plan for and ensure compliance of multiple employer welfare arrangements (MEWAs) that often arise in organizational structures that are implemented to comply with the prohibition of the corporate practice of medicine. The experience of the team runs the gamut for all employee benefits and compensatory arrangements (including executive and equity compensation) and the nuances of developing models for compensating medical professionals.

Labor and Employment

Sheppard Mullin maintains one of the most highly respected Labor and Employment practices in the country, and the largest on the West Coast. Our attorneys represent healthcare employers and their trade associations in providing advice to the industry and managing a number of high profile court cases and administrative actions.

- Covenants not to compete are a critical part of healthcare purchase and sale transactions. We regularly analyze proposed restrictive covenants, negotiate and document them and advise on possible exits from noncompete restrictions. We are familiar with the negotiation positions of all the leading physician group buyers with respect to physician noncompetition agreements.
- Our legal counsel for healthcare organizations includes defending employee termination and contract actions to discrimination and harassment claims before federal and state agencies and courts across the country.
- It also includes ERISA and other employee benefit claims.
- We represent clients in class action and multi-plaintiff litigation before courts and administrative agencies at the federal, state and local levels.
- Sheppard Mullin also advises healthcare employers in traditional labor matters. We have been involved with many of the major union organizing campaigns in the healthcare industry. Our attorneys represent healthcare clients before the National Labor Relations Board in connection with unfair labor practice charges, and recently authored an amicus brief to the United States Supreme Court on a traditional labor law issue of vital importance to the healthcare industry.

Emerging Growth/Venture Capital

Sheppard Mullin is a leading law firm in representing emerging and high growth healthcare companies and venture capital funds. Our experience is evidenced by the high level of assistance we provide to our clients in forming, structuring, financing and growing new companies. We understand the needs of a rapidly expanding commercial enterprise and provide timely and cost-effective legal advice and availability when and where it is needed.

We have assisted with a wide range of legal services geared towards development and growth, such as:

- Reviewing business plans and evaluating key strengths and weaknesses
- Company formation, including selecting the most appropriate type of entity
- Corporate governance
- Purchase agreements and private placement offering documents
- Employment agreements, employee incentive plans, employee benefits counsel and employment law compliance
- Angel financings, venture capital financings, equipment financing and joint development arrangements
- Patent, copyright, trademark and licensing matters
- Internet and e-commerce related advice
- Joint ventures and strategic partnerships
- Mergers and acquisitions, IPOs and secondary transactions
- Tax planning and succession planning
- Litigation

We provide more than just legal advice:

- Our firm's established presence in the market enables us to provide added benefits to clients in their quest for financing and potential co-investors. This assistance can range from introductions to funding sources and bankers to negotiating and documenting the terms of the investment.
- With offices around the world, we maintain a strong network of relationships with VCs, entrepreneurs and third-party experts in the startup ecosystem.
- The monthly Sheppard Emerging Company Webinar Program focuses on the legal issues faced by startup and emerging growth companies.
- We are familiar with emerging trends and can speak authoritatively on how proposed terms compare to the current market.

Capital Markets and IPOs

Our capital markets lawyers advise issuers, investment banks and investors in public and private capital markets transactions globally. A number of our capital markets attorneys have experience as senior executive officers or securities counsel for publicly traded companies. We offer practical and creative solutions to companies accessing the public and private capital markets. With deep regulatory expertise, industry knowledge and intimate familiarity with our clients and their goals, we help them rapidly execute opportunities when the market windows are open, assess and mitigate risks and maximize returns.

As a complement to our Capital Markets practice, our securities lawyers assist our public reporting clients in all aspects of SEC and stock exchange filing, disclosure and reporting obligations. We address the wide range of issues that confront a public company, as well as its board of directors, management and shareholders. We believe effective public reporting and corporate governance are among the most powerful tools available to advance an organization's mission and improve its attractiveness to capital markets investors.

Capital Markets Services

- Initial Public Offerings
- Registered Direct Offerings, Universal Shelves, Takedowns
- Rule 144A Offerings
- PIPEs and Other Private Placements
- Regulation S Offerings, EB-5 Offerings and Other Foreign Securities Transactions
- Debt Exchanges/Tender Offers
- High-Yield Debt Offerings
- Investment-Grade Debt Offerings
- Restructurings
- Spin-Offs and Other Carve-Out Transactions
- SPACs

Ongoing Public Company Services

- Mergers, acquisitions, spin-offs and going-private transactions
- Corporate governance, including Sarbanes-Oxley and Dodd-Frank compliance
- SEC, NYSE, NASDAQ, LSE and AIM reporting and disclosure requirements for US and non-US issuers
- Audit, compensation and governance committee matters
- Internal investigations
- Fairness opinions
- Contested shareholder proposals
- Directors' and officers' liability and insurance
- Executive compensation and employee benefits
- Supply chain management issues

Certificate of Need

We offer clients a full-service regulatory, reimbursement and licensing practice, including certificate of need processes. Our compliance and white collar/false claims practices are very active. On the compliance side, we provide licensing, regulatory and reimbursement advice to a broad range of healthcare providers. We regularly are involved in licensing, accreditation and survey/audit issues, including many “bet the company” situations. Our white collar/false claims practice has multiple multimillion-dollar cases relating to outpatient surgery centers, DME providers and hospital systems.

Women in Healthcare Leadership Collaborative

Sheppard Mullin's Women in Healthcare Leadership Collaborative (“WHLC”) is an innovative, exclusive national leadership initiative designed to support women who are in or are advancing into leadership positions within the healthcare and life sciences industries.

Drawing upon Sheppard Mullin's nationally-ranked healthcare law practice and the firm's leadership in diversity, equity and inclusion, WHLC provides its members with critical industry insights and unique quality networking opportunities.

Membership in WHLC is by invitation only. If you or someone you know would like to join WHLC, please contact whlc@sheppardmullin.com.