



Local Connections. Global Influence.

Healthcare



Why Choose Us

Our Multifaceted and Innovative Team Can Help You Surpass Your Goals

Our Healthcare Industry Group provides exceptional legal, regulatory, transactional, legislative and strategic counsel on a wide range of industry issues to healthcare-related entities around the globe. Our transactional specialists have completed hundreds of deals across the industry, ranging from company formation, to mergers, acquisitions and divestitures, and from corporate, public or project finance matters, through to workouts. Our litigators have extensive experience advocating for their clients in courts and arbitrations across the nation and have helped to develop key legal precedents guiding businesses today. Our public policy advocates are helping to shape the laws that will affect healthcare entities for years to come.

Our team specializes in multidisciplinary strategies that integrate our legal, public policy, commercial and technical expertise with the resources of a full-service, global firm. Our transactional specialists, litigators and public policy advisors can collaborate to propose creative solutions to achieve excellent results for clients – all with the single-source responsiveness that clients value. Our focus on creativity, innovation and insight is balanced against a sound focus on the law and a deep understanding of the dynamic business of healthcare. By developing a keen understanding of your business and strategic objectives, we are able to ensure we provide astute advice that will best enable you to navigate the challenges of this dynamic and quickly changing industry.

We have the specialized skills to advise on healthcare innovations and breakthrough technology (including providing patent prosecution and portfolio management), global data privacy and cybersecurity compliance, funding healthcare initiatives, antitrust matters, healthcare finance transactions, coverage and reimbursement, fraud, waste and abuse concerns and clinical trials management. We also advise and represent healthcare clients on matters involving real estate, construction, labor and employment, pharmaceutical and medical device product liability defense, and much more.

A Collaborative Approach Focused on You

We stress the importance of collaboration across practices and disciplines, as well as among our many locations. This enables us to draw expertise from numerous backgrounds and specialties for the ultimate benefit of our clients. Many find that our global footprint provides an excellent match for their business model, but we also focus on the local needs of clients operating within nations and regions with the same commitment and vigor. Our practice structure means we can bring you seamless, coordinated legal advice and advocacy on a cost-effective basis, wherever you may need it, and we arrange our client service teams to ensure we meet the unique needs of your representation.

We have long been leaders in providing a wide range of services to healthcare organizations, helping our clients to capitalize on opportunities and handle the challenges of a competitive and volatile business environment. We pride ourselves on providing practical real-world advice, not just a list of options from which to choose. We are able to do this because we are so familiar with the industry and take the time to understand your needs and priorities.

Areas of Expertise

Healthcare Policy

We are on the front lines of cultivating healthcare legislation and regulation. Nationally recognized for our sophisticated knowledge of these intricate issues, we have strong ties to leading policymakers and an impressive track record of success. This reputation can be attributed to many factors, notably, our longstanding working relationships with members of Congress and senior staff on each of the House and Senate health-related committees, as well as with congressional leadership. This valuable network, paired with our substantive legal, regulatory and policy expertise, enables us to achieve client goals.

These relationships often enable us to achieve clients' desired changes to statutory and committee report language. They are particularly useful in preventing unintended or adverse consequences. Members of our team often participate in the development of legislation on issues of concern to our clients and are consulted frequently as a resource for policy analysis.

Our team encompasses a diverse policy and regulatory practice. We develop and execute client strategies by engaging a variety of federal agencies, including the Centers for Medicare and Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration, National Institutes of Health (NIH), Food and Drug Administration (FDA), Federal Trade Commission (FTC) and Department of Defense (DOD). We regularly interact with key decision-making authorities, such as the Office of Management and Budget, Congressional Budget Office, Medicare Payment Advisory Commission, and Medicaid and CHIP Payment and Access Commission. Our practice also has a unique history of building and managing large coalitions in the healthcare sector. Our deep understanding of legislative and regulatory processes, coupled with our ability to manage the coalition format, has enabled us to help large coalitions achieve impressive victories repeatedly.

Not only does the Affordable Care Act continue to be subject to change, but Congress and the Executive Branch also continue to put forward new laws and regulations governing healthcare, insurance and government programs. Our team strategically positions clients to navigate the new opportunities and challenges that emerge from revolving reform regulations. Our broad-based expertise, gained by working in the private sector and with key government agencies, ensures that clients achieve their often-complex business goals. We are well positioned to address the myriad healthcare policy issues affecting providers, employers, suppliers, beneficiary groups, state and local governments, insurance companies, drug and device manufacturers, investors and other relevant stakeholders.

We are actively engaged in the ongoing, reform-related rulemaking processes and provide regular analyses of impactful guidance and regulations. Our strong presence on Capitol Hill permits the consistent implementation of defensive and offensive strategies to support our clients' best interests. We also maintain close ties with trade associations and stakeholder coalitions that affect our clients by driving legislative and regulatory changes.

Our Clients

- Academic medical centers
- Accountable care organizations (ACOs)
- Ambulatory surgical facilities
- Assisted living facilities
- Biotechnology, pharmaceutical and medical device manufacturers and distributors
- Clinically integrated networks
- Community health centers
- Dialysis centers
- Electronic health record (EHR) vendors
- Faculty practice plans
- Governments and sovereign powers
- Health information companies
- Healthcare insurers and health plans
- Health maintenance organizations
- Home health agencies
- Hospices
- Hospital systems and management companies
- Hospitals (general, special, religiously affiliated and teaching)
- Industry and professional trade associations
- Laboratories
- Managed care organizations
- Medical staffs
- Medical transportation companies
- Not-for-profit organizations
- Nursing homes and long-term care facilities
- Pharmacy benefits managers
- Physicians and physician group practices
- Private equity, venture capital and sovereign wealth funds
- Research service providers
- Shared service organizations
- Substance abuse treatment providers



Corporate and Transactional

We are recognized leaders in assisting industry clients with a range of commercial transactions and requirements. We have handled these matters for more than a century and routinely advise clients engaged in every type of corporate transaction, offering legal advice on corporate mandates across the spectrum, ranging from smaller, more straightforward deals to complex multibillion-dollar, multijurisdictional and multidisciplinary transactions. This includes mergers, acquisitions and divestitures, transfers of ownership, asset purchases and the integration of existing facilities and related businesses. We provide integrated management of the commercial and regulatory issues inherent in a wide variety of transactions. This involves providing the full range of legal services necessary to complete a particular transaction, in a cost-effective, timely manner, based on an extensive resume of prior deals. Our experience with non-profit hospital transactions, for example, covers an array of structures and relationships, including hospital-to-hospital affiliations, sole membership substitutions, special member arrangements, joint operating arrangements and asset transactions, to name but a few. We have extensive experience in private equity transactions involving healthcare providers of all types. We also have substantial experience in helping start-up companies to secure public and private financing, whether through private equity funds, venture capitalists or alternative sources, such as grants or partnership agreements.



Data Privacy

Our team counsels clients on data breaches and data breach notification requirements (including hundreds of breaches in the healthcare sector alone, ranging from small to large-scale breaches). We also provide proactive compliance advice that integrates legal requirements, technical expertise and leveraged “practical” focus using our experience in working with a wide range of providers, plans and other entities that operate in the healthcare sector. We have helped many clients develop or strengthen their privacy and cybersecurity programs to efficiently and effectively manage risk through risk assessments, incident response plan reviews and updates, and vendor and contract management, as well as tabletop exercises to help clients practice responding to hypothetical security incidents.



We have extensive experience helping healthcare companies and providers navigate the complex regulatory landscape. This includes guidance for regulations imposed under the Health Information Technology for Economic and Clinical Health (HITECH) Act, HIPAA, federal part 2 regulations, state laws governing sensitive information (e.g., mental health, HIV/AIDS, etc.), the Federal Trade Commission Act, Payment Card Industry standards and other laws, regulations and best practices.

We also help clients manage risk by leveraging our relationships with key state and federal regulators (including the Office for Civil Rights) to obtain informal guidance, where necessary, and help clients focus on the issues that are most likely to trigger scrutiny. Our experience working with a broad cross-section of the healthcare industry also enables us to provide important industry context and benchmark practices against other companies to avoid less useful “check the box” exercises.



Further, we help healthcare organizations to do business on a global scale and other clients dealing with international healthcare-related issues to achieve compliance with international cross-border data privacy rules, such as the European Union Privacy Directive.

Fraud and Abuse and False Claims Compliance, Counseling, Litigation and White Collar Defense

We bring you a full range of services relating to analyzing healthcare fraud and abuse statutes and regulations, including the FCA and its *qui tam* (whistleblower) provisions, the Anti-Kickback Statute, the Self-Referral (Stark) Laws and the Food, Drug and Cosmetic Act (FDCA). Our experienced professionals have particular expertise in counseling clients on establishing and improving compliance programs and proactively addressing and mitigating related issues.

Our lawyers previously worked as US Attorney's and Assistant US Attorney's prosecuting healthcare fraud claims against healthcare providers and pharmacies. This experience makes them an invaluable advocate for any healthcare entity facing a potential or current investigation by a government agency. Our lawyers counsel and defend clients against allegations of fraud and abuse and antitrust price-fixing, and assist them as they navigate healthcare regulatory and licensure challenges at both the federal and state levels. We advise clients on liability and risk mitigation options and negotiate corporate integrity agreements.

We are also well versed in handling complex civil, criminal and administrative matters for various healthcare and life sciences clients. We are able to defend clients in civil and criminal investigations and actions initiated by the government, including the DOJ, US Attorneys' Offices, Department of Health and Human Services Office of Inspector General (HHS-OIG), Federal Bureau of Investigations, state Medicaid Fraud Control Units, and other federal and state regulators.

Litigation

We offer clients an exceptional combination of litigation and healthcare capabilities throughout the US to resolve multifaceted legal matters with a deep understanding of the healthcare sector. We counsel and defend healthcare clients faced with pending and threatened litigation and governmental investigations stemming from sweeping regulatory reform and significant advancements in science and technologies focused on patient care and services. We represent clients in state and federal courts through jury and bench trials, in administrative procedures and hearings, and through the appellate process. These cases include a wide variety of lawsuits, including complex, bet-the-company litigation. We advise clients on liability and risk mitigation options related to corporate agreements, such as mergers, acquisitions and affiliations of all kinds, and on precedent-setting issues and rules shaping the industry, such as the establishment of, and guidelines for, ACOs, clinically integrated networks (CINs) and direct contracting with self-insured businesses.





Competition – Antitrust

Our Competition – Antitrust Practice offers practical, hands-on guidance and innovative solutions to domestic and international antitrust problems. Our antitrust lawyers have significant experience in counseling healthcare organizations and physicians on the antitrust aspects of affiliations and mergers, acquisitions and joint ventures (including single-specialty or large multispecialty physician groups seeking to affiliate with other physicians or groups and clinical integration). We have frequently represented healthcare clients before the FTC, DOJ and state competition authorities in connection with mergers and acquisitions and government investigations, and we are not afraid to litigate antitrust and unfair trade practice concerns. We advise clients on antitrust issues involving:

- Managed care contracting
- Merger/acquisition/affiliation analysis
- Messenger model formation and operation
- Monopolies
- Pay-for-performance programs
- Peer review
- Provider network formation and operation
- Staff privileges and peer review activities
- Joint contracting and negotiation
- Alternative delivery systems (including ACOs)
- Clinical integration strategies
- Government (state and federal) investigations
- Hart-Scott-Rodino (HSR) filings
- Joint operating companies
- Joint ventures and provider collaborations

Finance

We regularly advise governments and public-private partnerships, including project sponsors and awarding authorities, on healthcare infrastructure projects around the world, along with acting for lenders and borrowers on project funding. Our Public & Infrastructure Finance Practice has an excellent reputation and seasoned experience related to tax-exempt financing of non-profit healthcare systems. We can also offer clients extensive experience in mainstream private equity transactions, growth and venture capital investments, mezzanine financings and turnaround situations. Our capital markets and financial services expertise provides clients with counsel on debt and equity funding, including public offerings and a variety of bank and debt financing.

Health IT and Communications

Healthcare providers, payers and patients are increasingly turning to (and vendors are seeking to offer) technological solutions to facilitate data sharing, care coordination and other activities designed to improve quality, lower costs and enhance the patient experience. However, the patchwork of applicable laws and data security risks associated with handling sensitive healthcare information requires careful consideration and planning. Our healthcare privacy and cybersecurity lawyers have extensive experience helping healthcare companies navigate these laws, manage risks, utilize technology, and facilitate data exchanges.

Regulatory Compliance

Tougher international, federal and state regulations challenge healthcare, health insurance and life sciences industry players every day. Our lawyers are familiar with all relevant regulations and can help with compliance issues and in negotiations with regulators and investigators in Washington DC, within states and around the world. We develop and execute clients' offensive and defensive regulatory strategies by engaging CMS, CDC, HRSA, HHS-OIG, NIH, FDA, FTC, DOD, state departments of insurance, state attorneys general and other state agencies, as well as similar agencies outside the US. Our experience extends across a wide range of issues and regulations, including:

- Hospital and provider networks
- Import/export issues
- Internal investigations
- Medicare, Medicaid and children's health insurance program coverage and reimbursement
- Mergers, acquisitions and divestitures
- National and state healthcare regulations
- Off-label uses for drugs and medical devices
- Product recalls and market withdrawals
- Responding to subpoenas
- Advertising and promotion
- Agency enforcement
- Antibribery and anticorruption
- Clinical best practices
- Dietary supplements
- Drugs and biologics
- Food and drug regulation
- Foreign market entry
- Good Manufacturing Practice and Quality System Regulation
- Hospital finance – tax exempt and taxable

Insurance

We have excellent insurance regulatory and transactional lawyers, including a former insurance commissioner. They work with health insurers, health maintenance organizations (HMOs), Medicare Advantage and prescription drug plans, Medicaid managed care organizations, pharmacy benefit managers and other managed care organizations in obtaining necessary regulatory approvals and licenses, as well as assist with market conduct examinations and other investigations by state departments of insurance. We also have a broad experience base in representing provider-owned insurance plans and navigating the related business and regulatory issues. Added to this, our experience in representing many different parties in healthcare systems enables us to better understand issues and concerns of providers and those with whom they interact.

We assist our health insurance clients with a full range of regulatory and compliance issues and represent them before government and regulatory agencies, advocating their interests and advising on best practices. We help our clients with insurance holding company regulations, corporate transactions, risk sharing arrangements, strategic planning, market analysis, defense of regulatory actions, corporate governance best practices, innovation and product development, reinsurance and risk adjustment programs, distribution channels and intermediaries, data reporting, and financial examinations and oversight. Our long history of bringing insurance companies legal counsel on corporate, regulatory and operational issues gives us a thorough understanding of their culture and perspective.



Our long experience and breadth of practice ensure you receive top-quality service across areas including:

Industry Issues

- Access to capital
- Delivery system reform
- Environmental
- Fraud and abuse
- Health information exchanges
- Health information technology
- International healthcare
- Legislative liaison
- Liability/risk
- Medical staff matters
- Patients' rights
- Regulatory matters
- Sponsorship matters
- Third-party reimbursement
- General Corporate Services
- Antitrust
- Business planning
- Business transactions/contracts
- Corporate organization
- Employee benefits
- Equity financings
- Intellectual property
- IT outsourcing
- Labor and employment
- Real estate
- Tax-exempt financing
- Tax matters
- Workouts/reorganization

Medicare and Medicaid

A core focus of our practice involves helping clients navigate the overlapping statutes, regulations and agency directives governing Medicare and Medicaid coverage and reimbursement. Through sophisticated counseling, analysis and advocacy, we can help healthcare providers obtain coverage and adequate reimbursement for products and services under these programs. We can also help our health insurance clients to understand and implement Medicare and Medicaid laws, regulations and contractual requirements that apply to their insurance products, market activities and operations. Our litigation and dispute resolution lawyers are also well versed in Medicare and Medicaid payment-related litigation, regularly representing both individual and group clients before the Provider Reimbursement Review Board and in federal and state courts and arbitrations. Our healthcare litigators also have a long and successful record of challenging the validity of federal and state regulations, both procedural and substantive, that affect payment for healthcare services rendered.

Intellectual Property

Our lawyers are adept at guiding patent applications through the approval process and obtaining broad, valuable patent protection, gaining trademark protection, drafting and implementing licensing and distribution agreements, and litigating to enforce patent or trademark rights or to defend against the claims of others.

International Dispute Resolution (IDR)

Healthcare businesses working across borders need sophisticated IDR counsel when conflicts arise. This is the case in business transactions and contract disputes or disputes related to foreign patients. We are one of only a small number of legal practices able to serve the IDR needs of clients on a truly global basis, with long-established practice groups throughout the Americas, Europe and Asia Pacific, and significant experience in front of a variety of international tribunals.

International Healthcare – Transactions and Infrastructure

We are actively engaged in cross-border and international healthcare transactions, often with the ability to bring extensive knowledge of local law to the documentation and implementation of our clients' interests. We are also experienced advisors to sovereigns and other government interests, particularly as relates to the creation or modernization of legal and regulatory healthcare infrastructure.

Clinical Trials

Our Healthcare and Life Sciences teams work closely with clients to support the timely, efficient and compliant launch of multinational clinical trials. These trials support marketing approval applications and meet post-marketing clinical investigation requirements around the world. We help pharmaceutical, biotechnology and medical device companies, hospitals, pharmacies, contract research organizations and academic research institutions to conduct clinical trials in emerging jurisdictions of interest, including Russia, Poland, Hungary, China, Brazil, Argentina and Chile, as well as providing support in the US, Japan, the European Union (EU), the Middle East and Africa.

Labor and Employment

In matters of employment, we assist hospitals, medical centers, long-term care and assisted living providers, physician groups and other healthcare clients. These legal matters can range from employment litigation and risk management to discrimination and harassment, executive agreements and wellness programs. We also advise on the sponsorship and employment of foreign nationals throughout the world.

US Food and Drug Administration

We represent clients in all FDA-regulated areas, including prescription drugs, biologics, over-the-counter drugs, nutritional supplements, food, medical devices and cosmetics. Our work with clients spans a wide range of matters. This includes advising on effective strategies to obtain approval to market a new product, assisting in determining which regulatory pathway to follow, assessing regulatory and business risks associated with a particular strategy, responding to and defending enforcement matters, initiating and participating in rulemakings, and counseling on public policy issues, as well as cost-effective due diligence.

Products Liability

Our team is known for its expertise in the field of pharmaceutical and medical products liability. We often represent companies in complex litigation involving bodily injury, property damage or economic loss allegedly caused by defective products, pharmaceuticals, cardiac devices or exposure to toxic substances. We can serve as trial, appellate and national coordinating counsel in high-visibility product liability cases, defending claims against manufacturers and sellers of prescription medications, over-the-counter products and medical devices.

Real Estate

We represent developers, contractors, major utilities, commercial lenders and financing institutions, governments and governmental agencies in real estate matters in the healthcare and life sciences sector. This includes property acquisitions, planning, construction and project funding. Our lawyers can share the benefit of their broad experience, having participated in all phases of the real estate development process, from both business and legal perspectives. We are familiar with all applicable governmental regulatory matters and environmental concerns that need to be confronted at every stage of real estate development.

Telemedicine and Telehealth

Telemedicine and telehealth technologies, which expand access to care and enable patients to stay in their homes and communities, are important to the continued evolution of healthcare systems. Our Healthcare Industry Group has extensive experience helping clients address the legal intricacies and unique nuances of the law in adopting and implementing telemedicine and telehealth networks. Our legal services in this area help clients navigate the complex web of state, federal and international laws and regulations that affect the provision of care and exchange of electronic patient information. We offer not only decades of experience working with healthcare providers in individual states, but also a national and global perspective on how other jurisdictions have advanced the development of telehealth services. Among other things, we serve as primary counsel for hospitals and physicians and as deal counsel for telehealth service-related joint ventures.

Taxation and Benefits

Healthcare clients look to us for advice on tax exemption matters, community benefit and the new IRC §501(r) requirements, unrelated business taxable income, reorganization and diversification, physician recruitment programs, charitable giving vehicles, and audits and appeals. We can also provide insight and guidance on any employee benefits and pension scheme matters in the countries in which healthcare clients are investing for growth.



Thought Leadership

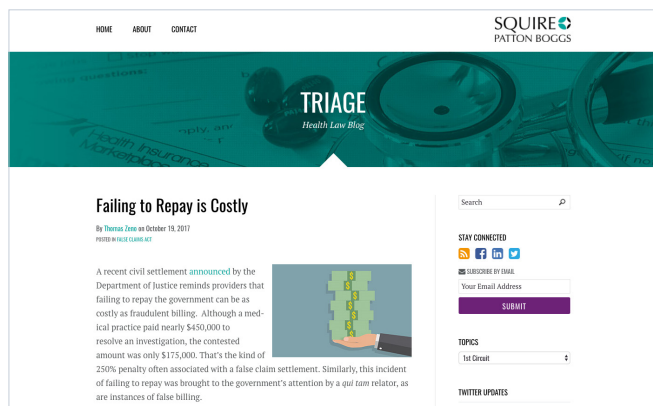
Always in tune with developments in the healthcare industry, we respond to breaking news events through briefings and alerts emailed to our clients or posted on our website and various blogs. Typical developments may include new legislation, impending laws and court rulings that have a potential impact on the organizations we represent. These swiftly executed communications give clients an overview of the event and analysis of its possible effects on their business. Our lawyers are frequent speakers, panelists and moderators at major industry conferences, webinars and other events, authors of white papers and articles for industry publications, and sought-after commentators by the media on evolving industry topics and issues.

Seminars and Workshops

Throughout the year, we offer clients the opportunity to meet with members of our Healthcare and Life Sciences teams and other industry professionals at firm-hosted seminars and workshops that provide insight into current issues and hot topics within the industry. Details about all of our previous and upcoming events are posted to the Insights & Events page on our website.

Triage Health Law Blog

Our *Triage Health Law* blog aims to foster discussion about the rapidly evolving healthcare industry in the climate of global reform. Although it focuses on the new challenges and opportunities presented by recent government action, it also examines other aspects of today's healthcare and life sciences industries. Regular contributors from across the firm share insights on recent and evolving topics from a number of practice areas.



Distinctions

Ranked in *Chambers USA* for Healthcare and Insurance

Recognized in *The Legal 500 EMEA* 2023 for Healthcare & Life Sciences and Insurance

Recognized in *The Legal 500 UK* 2023 for Healthcare & Life Sciences

Nationally Ranked for Health Care Law in the U.S. News & World Report

Ranked as one of the larger healthcare law firms in Modern Healthcare

For the second year in a row, tier 2 National Ranking for Health Care Law in the *U.S. News & World Report* 2021 "Best Law Firm" Rankings, noting our Cincinnati, Columbus and Phoenix offices in particular

The Legal 500 Europe, Middle East & Africa – 2022 France ranking: recommended for Healthcare and Life Sciences

Ranked as one of the top healthcare law firms by the American Health Lawyers Association

The Best Lawyers in America 2011-20, including three partners ranked in Healthcare for 2020

Ranked as one of the larger healthcare law firms in Modern Healthcare's 2021 survey

Refinitiv's Annual Report for 2019, as bond counsel, the firm achieved rankings of 6th nationally for all issues and 5th nationally for healthcare finance issues

How Can We Help You?

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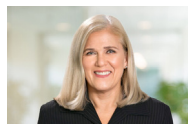
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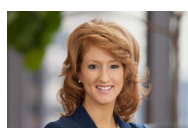
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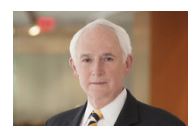
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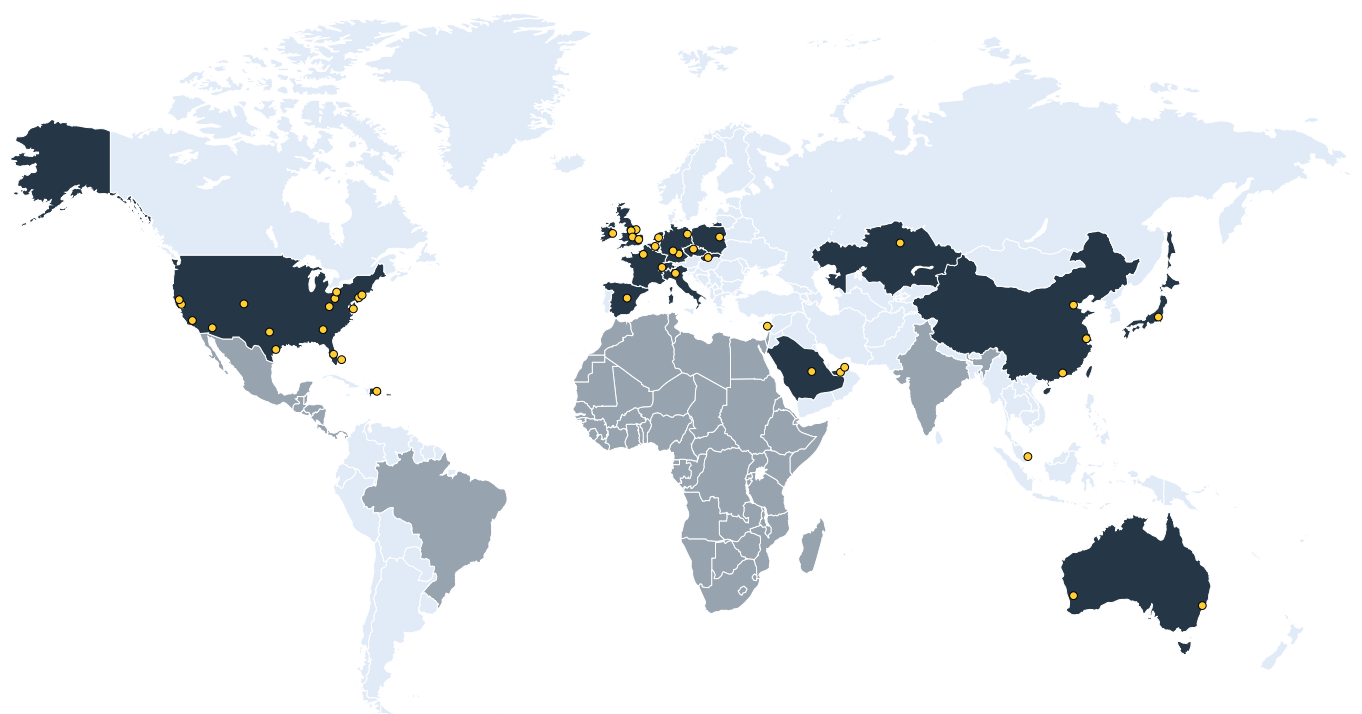
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We Are Where You Are

More Than 40 Offices Across Four Continents



● Squire Patton Boggs Locations

● Regional Desks and Strategic Alliances

Our Locations

Abu Dhabi	Brussels	Hong Kong	New York	Singapore
Amsterdam	Cincinnati	Houston	Palo Alto	Sydney
Astana	Cleveland	Leeds	Paris	Tampa
Atlanta	Columbus	London	Perth	Tokyo
Beijing	Dallas	Los Angeles	Phoenix	Warsaw
Beirut	Denver	Madrid	Prague	Washington DC
Berlin	Dubai	Manchester	Riyadh	
Birmingham	Dublin	Miami	San Francisco	
Böblingen	Frankfurt	Milan	Santo Domingo	
Bratislava	Geneva	New Jersey	Shanghai	

Regional Desks and Strategic Alliances

Africa	India
Brazil	Israel
Caribbean/Central America	Mexico

