



Capability Statement

Consulting Services

A Relentless Focus on Our Clients' Objectives



The Connect 4 team has the experience that comes from running companies' reimbursement functions, working in nationally-recognized law firms, supporting dozens of product launches, and working in government – both in Congress and the Executive Branch (HHS/CMS).

We also have an extensive network of relationships among stakeholders critical to our clients' needs, a deep bench of strong partners, and solid project management experience to support our clients.

Below is a summary of the 25+ years of experience each of us brings in the field of strategic reimbursement, market access, launch planning, and hotline support work, as well as the federal and state government affairs and advocacy expertise needed to advise on aligning on reimbursement strategies and tactics.

Professional Information

About Connect 4

Connect 4 Strategies, LLC provides strategic consulting services for patient advocacy organizations, life science companies, medical societies, and trade associations. Connect 4 leverages over 25 years of corporate, nonprofit, and government experience in the reimbursement, market access, legislative and regulatory health policy arena.

Our deep understanding of the ever-changing

policy environment and respect for the government's staff and principal goals allows us to bridge the stakeholder communication gap to create winning solutions to complex challenges.

We bring a proven ability to bring together disparate stakeholders, actively listen and manage a range of perspectives, find common ground, craft innovative solutions, and create pathways for successful results.

What Sets Connect 4 Apart?

Connect 4 uniquely builds a team around each client's needs – distinctly qualified and relentlessly driven to meet their **objectives**. Connect 4's leadership assesses each client's needs, near- and long-term challenges, goals, and priorities. We then assemble and manage a team to meet the client's goals and exceed their expectations. In other words, the client never pays for the overhead of team members not essential to accomplishing the tasks most important to their organization. Each client also benefits from a large and established network of stakeholders across health care disciplines that consistently provides valuable insights for successful strategies.

We bring a wealth of experience working cross-functionally in a corporate environment, as well as with advocacy organizations and key trade associations. Our in-house experience in companies and patient/provider organizations means we have walked in our client's shoes and know how to serve a step above.



Core Capabilities





Representative Projects



Coalition-Building and Facilitation

- ✓ Develop policy positions for provider group whose members have competing interests, facilitate negotiation and focus on shared interests
- ✓ Facilitate and direct formation of a patient coalition as part of a disease awareness campaign.
- ✓ Work across CMS, CDC, and FDA to further a cross-agency dialogue and clarify agency roles related to new vaccine launch, including successful adoption of a risk standard for expediting vaccine CPT codes.
- ✓ Lead extensive emerging trends analysis and white paper impacting the future of oncology practices.
- ✓ Build enduring coalition of nontraditional stakeholders to ensure health equity perspectives were well represented.
- ✓ Build a successful coalition of patients, providers, pharmaceutical, and medical device companies to work with CMS as the agency sought to establish a prospective payment system in the Medicare outpatient setting.
- ✓ Bring together all major patient and provider stakeholders in a disease state to collectively spearhead new codes and payment.
- ✓ Coalesce local, regional, and national patient voices in a successful effort to add a disease to a federal program incentivizing innovation, working across historically disenfranchised and fractured groups.



Regulatory and Legislative Initiatives

- ✓ Successfully lead negotiations for passage of numerous bills, ensuing passage of bipartisan, bicameral legislation.
- ✓ Establish and direct all lobbying, regulatory, and public policy activities for a trade association representing community cancer centers.
- ✓ Serve as spokesperson on all legislative and regulatory policy matters, giving keynote addresses at over 30 varied forums each year on behalf of a medical society.
- ✓ Work closely with CMS and HHS to address patient concerns immediately after Covid-19 pandemic was declared an emergency, aligning disparate stakeholders to achieve early Covid flexibilities.
- ✓ After years of failed efforts, successfully lead an effort to raise the patient cap on substance use disorder prescribing, working across medical societies, FDA, CMS, SAMHSA, CDC, and OMB.
- ✓ Educate Congressional offices as well as FDA, CMS, HHS, and align patient and provider groups regarding reimbursement for digital therapeutics. Legal and policy analysis, draft legislation, talking points, one pagers, op-eds, and letters.
- ✓ Successfully create and negotiate a multi-prong legislative agenda to ensure long term revitalization and focus on children's health care..



Reimbursement and Market Access

- ✓ Develop comprehensive reimbursement landscape assessments, including analysis of coverage, coding and payment across the patient journey, including each decisionmaker in the treatment planning process, payer and patient mix, scenarios for provider uptake, provider economics, value assessment planning, and gap analysis and of clinical guidelines and quality measures.
- ✓ Guide patient group and life science companies' leadership through dozens of successful interactions with key government officials, paving the way for credible and thoughtful partnerships.
- ✓ Secure separate HCPCS codes for IM and IV formulations to delay adverse payment consequences.
- ✓ Successfully navigate and resolve CMS-initiated NCD/CEDs for companies, medical societies and academic centers.
- ✓ Provide strategic counsel on coding, across ICD-10, HCPCS, and CPT codes.
- ✓ Anticipate opportunities, develop and successfully execute strategies related to AHRQ, USP and USPSTF.



Launch Planning

- ✓ Successfully craft and execute multi-prong strategy to differentiate products for reimbursement purposes.
- ✓ Obtain an exception to retain 95% of AWP for physician offices during transition to ASP-based pricing without supporting data.
- ✓ Identify significant vulnerabilities in payment due to planned simultaneous launch of IM and IV formulations
- ✓ Create and Implement approaches to New Technology Add On Payments
- ✓ Create Pricing and Access Strategies, Tutorials, Webinar Content, Panel Discussions, White Papers
- ✓ Identify significant reimbursement challenges, and work in collaboration with Client's Medical and Regulatory team,
- ✓ Create a lexicon for FDA communications and submissions that anticipated and warded off later those challenges
- ✓ Develop survey instruments, interview, and collect primary research data that ultimately redirected Client's launch planning, refocusing on different providers as treatment decision makers
- ✓ Create and execute disease awareness strategies that look ahead to and resolve anticipated regulatory challenges ahead of approval and launch.



Saira Sultan, JD

President and CEO

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Public Policy Expertise

Saira Sultan has represented corporate, nonprofit, and government interests in the legislative and reimbursement health policy arena for more than 25 years in Washington, D.C. She has had repeated success in designing reimbursement solutions by identifying and creating advocacy opportunities and translating them into strategic legislative and administrative/regulatory results.

With more than two decades of experience working with drug manufacturers as well as patient and provider organizations on reimbursement policy issues, Saira has successfully lobbied policymakers to ensure access to treatments, protocols for care (i.e., emergency rooms and physician offices), and appropriate incentives for third parties developing new treatments and for providers making treatment decisions.

Saira opened the Government Affairs office for Sanofi, leading all lobbying and policy efforts for the company. She also led all lobbying and policy efforts related to CMS for Medtronic, and ran the lobbying department for an association that represents cancer centers. In all three roles, her emphasis on market access ensured a strong connection to business-oriented reimbursement solutions. Saira's lobbying successes have relied on a deep understanding of and close working relationship with legal, market access, advocacy,

health outcomes, and commercial teams in pharmaceutical companies. This experience has been immensely helpful in guiding patient, provider, and payer support for a client's goals.

Finally, Saira has worked extensively with CMS, the FDA, and the Hill. Her insight and skill in working cross-functionally in a corporate environment, with advocacy organizations and key trade associations, serves her clients well.

After receiving her law degree from the University of Virginia, Saira gained valuable insights and experience through her work in the Ways and Means Committee, her role as senior legislative counsel for Senator Mike DeWine, and then as Chief Counsel to a Subcommittee of the Senate Health, Education, Labor, and Pensions (HELP) Committee. She handled all the health care issues under the Senate HELP Committee's jurisdiction, including extensive negotiations with FDA and industry on the Balanced Budget Act and the Food and Drug Administration Modernization Act. She spearheaded passage of the first Better Pharmaceuticals for Children Act.

Saira received her J.D. from the University of Virginia School of Law, and is admitted to the Bar in both Maryland and District of Columbia.

M Kay Scanlan, JD

Senior Advisor

Reimbursement and Market Access Expertise

M Kay Scanlan has 20 years of health policy and reimbursement experience. As an HHS Office of General Counsel attorney representing CMS (then, HCFA), Kay has worked on a wide array of regulatory and reimbursement issues and policy initiatives, earning the Administrator's Award for Excellence in connection with her leadership on the Agency's clinical laboratory test negotiated rulemaking team. Following her work in the Office of General Counsel, Kay joined Arnold & Porter, where she was instrumental in delivering the creative strategies and high rates of success necessary to build a strong reputation for the Firm's new Healthcare Group.

Kay's expertise extends from preclinical stage to launch of new therapies, where her work has involved deep expertise in reimbursement and market landscape analyses, primary and secondary research in patient journeys as it relates to provider pharmacoeconomic incentives and clinical decision-making, regulatory impact analyses, strategy development, and Agency communications. Her understanding of CMS' processes, interests and goals fits Connect 4's vision of ensuring clients not only get strategies that resolve their concerns but are designed to be win for both client and agency. Clients appreciate this qualitative edge in a competitive market.

She has served on and facilitated payer advisory panels, contracted as an "expert advisor" for a major consulting firm, and represented a broad range of clients to include large and start-up

biotechnology manufacturers, medical device manufacturers, patient advocacy groups, a large Cancer Center, and a Medicare vendor. Her expertise extends from preclinical stage landscape analyses, through launch planning, regulatory impact analyses, portfolio strategy development, legislative drafting, "white paper" submissions, Medicare and Medicaid waivers, and Agency communications. Her understanding of CMS' processes, interests and goals fits Connect 4's vision of ensuring clients not only get strategies that resolve their concerns, but are designed to be a win for both client and agency. Clients appreciate this qualitative edge in a competitive market.

Kay received her J.D., *Order of the Coif*, from the University of Maryland where she subsequently served as an Adjunct Professor of Law, teaching healthcare law and Medicare and Medicaid policy.



Clients work **ONLY** with the principals that bring 25+ years of reimbursement, market access and supporting Advocacy and Policy experience.

Connect 4's network of experts means clients never pay for expertise they do not need.

Our network of seasoned professionals work closely together and allow us to assemble and lead a **CUSTOM-DESIGNED TEAM** for each client's unique needs to meet their goals and exceed their expectations.

We never offer cookie-cutter solutions or solutions that can only leverage a limited set of experiences.

Name and Address of Principal

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Founded in 2014, Connect 4 is a woman and minority owned S Corporation.
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Compliance and Additional Background

Connect 4 Strategies has a strict commitment to integrity, and operates in compliance with all laws and regulations governing its business and lobbying activities. The firm has not been involved in any bankruptcy or re-organization proceedings, nor has it been subject to any professional liability or professional malpractice claims or judgments.

