



Federal
Insights and
Advocacy



LEAVITT

PARTNERS

An HMA Company



FEDERAL INSIGHTS AND ADVOCACY

Congress and the Biden Administration continue to examine and advance significant, paradigm-changing health care policies, including drug pricing, Medicare insolvency, Medicaid reforms, insurance benefit redesign, value-based care, digital health, and provider payment. Organizations seeking to influence the outcome of these policy debates, and thrive in a new regulatory environment, must have the most current information, informed by partners who understand the legislative and regulatory processes, as well as the underlying policy under consideration.

Our Expertise

The Leavitt Partners team is comprised of experienced policymakers and staffers spanning the executive and legislative branches of government. Our team members have served as congressional staff and political appointees, and know firsthand the regulatory and legislative processes. Our staff also has deep policy expertise, having helped write significant health care legislation and regulation during their public service. We help health care organizations, from the most sophisticated multi-national organizations to the smallest local providers, navigate a turbulent, and often confusing, Washington, D.C.

Legislative Insights

Leavitt Partners' team has been at the forefront of health care policy development for more than three decades. We have been involved in developing most of the major health care legislation over that time, including the Medicare Modernization Act (established Medicare Part D), the Affordable Care Act, the Medicare Access and CHIP Reauthorization Act (MACRA), the 21st Century Cures Act, multiple FDA User Fee Acts, the Comprehensive Addiction and Recovery Act, the Drug Supply Chain Security Act, and the Pandemic and All-Hazards Preparedness Act and its reauthorizations, multiple COVID-19 relief packages, to name a few.

Through these experiences, our team has built unparalleled expertise in issues impacting life-science organizations, providers, payers, patient advocacy and consumer organizations, and digital health innovators. We understand, and can help organizations navigate, the policy issues they confront and the often-confusing legislative process. We work with each organization to develop policy solutions to their unique challenges and specific advocacy strategies.

OUR SERVICES INCLUDE:

Congressional Insights

Real-time information and analysis on committees of jurisdiction and leadership action, including hearings, markups, and proposed legislation.

Policy Development

Complete policy building, including policy conceptualization and creation, legislative text development, and collateral formation.

Advocacy Strategy

Comprehensive advocacy planning and implementation to make sure messages cut through the noise on Capitol Hill.



WHO WE HELP

- » Associations
- » Biotechnology Firms
- » Employers
- » Foundations
- » Government
- » Health Care IT
- » Hospitals and Health Systems
- » Medical Device Manufacturers
- » Patients
- » Consumers
- » Payers
- » Pharmaceutical Companies
- » Physician Groups

WHERE WE COME FROM

- » House and Senate
- » Personal Offices and Committees
- » White House Offices and Health and Human Services
- » Democratic and Republican Offices
- » Private Sector and Trade Associations

ADMINISTRATION INSIGHTS

Leavitt Partners' staff directly participated in the administrative process in developing major regulations, sub-regulatory guidance, and statements of administrative policy. We anticipate the regulations, guidances, policies, and other executive actions that agencies are likely to issue. We provide organizations with a complete picture of the specific opportunities and implications that these actions will have.

OUR SERVICES INCLUDE:

Policy Intelligence

Real-time information tailored to a specific organization providing intelligence on various agency actions, including regulations, guidances, executive orders, meetings, and briefings by the White House, Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), Office of the National Coordinator for Health Information Technology (ONC), National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA).

Regulatory Strategy and Advocacy

Develop and implement regulatory policy, strategy, mapping, and advocacy.

Business-Specific Regulatory Impact Analysis

Policy assessment of how proposed and final rules, guidance, and other administrative action will impact organizations and sectors.

Comments on Administrative Action

Organization-specific comment preparation on regulations, guidance, and other administrative actions.

Our Experts



Mike Leavitt

Founder; Chair, Board of Managers, Leavitt Partners;
Co-Chair, Health Management Associates

Mike Leavitt is the founder of Leavitt Partners where he helps clients navigate the future as they transition to new and better models of care. In previous roles, Mike served in the Cabinet of President George W. Bush (as Administrator of the Environmental Protection Agency and Secretary of Health and Human Services) and as a three-time elected governor of Utah.



Vince Ventimiglia

CEO, Leavitt Partners

Vince Ventimiglia leads the Leavitt Partners D.C. office, including the firm's alliances and federal advocacy work. Vince brings over 35 years of administration, congressional, and health policy experience.

In previous roles, Vince was assistant secretary for legislation at the U.S. Department of Health and Human Services (HHS). Vince also served for a dozen years in leadership roles with the Senate Health Education Labor and Pensions (HELP) Committee and the Senate Budget Committee. Key policy areas include negotiating or drafting many of the FDA User Fee and other FDCA statutory changes, biodefense and pandemic preparedness initiatives, and Medicare regulatory initiatives. He serves on the Boards of several not-for-profit and public health organizations.



Clay Alspach

Principal, Leavitt Partners

Clay Alspach specializes in health care policy and advocacy related to the FDA, digital health, public health, pandemic preparedness, Medicare, Medicaid, and private health insurance. Prior to joining Leavitt Partners, Clay served as Chief Health Counsel for Chairman Fred Upton of the U.S. House of Representatives Energy and Commerce Committee.

Our Experts



Amy Bassano

Managing Director, Medicare, HMA

Amy Bassano has more than 20 years of experience developing organizational vision and strategic plans, designing, and implementing payment systems, and driving change in the health care delivery system. She joined HMA as managing director of Medicare services after serving as the deputy director for the Center for Medicare and Medicaid Innovation (CMMI) at the Centers for Medicare & Medicaid Services (CMS). As senior executive at the CMMI, she oversaw the development and implementation of value-based purchasing models for both Medicare and Medicaid including accountable care organizations, bundled payment programs, and specialty initiatives in oncology, kidney care, prescription drugs, state-based models and dual eligibles. Additionally, she collaborated with states, health plans, purchasers, and international organizations to lead the national and international movement to value in health care.



Laura Brown

Director, Leavitt Partners

Laura Brown provides federal policy counsel and analysis to clients and assists in managing multi-sector alliances. Her work focuses on issues related to FDA regulation, digital health, public health and the environment, and administrative procedure. Prior to joining Leavitt Partners, Laura was the Director of Educational Programs at the Food and Drug Law Institute (FDLI), where she led the team developing FDLI's conferences, educational programs, and webinars addressing all areas of food and drug law, working frequently with a variety of stakeholders including FDA, DOJ, FTC, industry, and public health.



Charlene Frizzera

Senior Advisor, Leavitt Partners

Charlene is an outstanding thought leader with exceptional operational knowledge surrounding the Centers for Medicare & Medicaid Services (CMS). Charlene served as acting administrator for CMS where she was responsible for leading the policy and operational aspects of CMS while executing the design and implementation plan for the recently implemented Affordable Care Act. Charlene's CMS career includes positions as Chief Operating Officer, Deputy Chief Operating Officer, and Deputy Director for the Center of Medicaid & State Operations.

Our Experts



Matt Gallivan

Director, Leavitt Partners

Matt Gallivan works with clients to advance forward-leaning health care policy that is focused on solving complex challenges. He previously was director of state and federal regulatory affairs for 3M Health Information Systems, and Matt has served as health policy director for Senator Bill Cassidy, M.D., where he oversaw the Senator's health policy work for the Senate Finance and Senate Health, Education, Labor (HELP), and Pensions Committees. Matt also oversaw the Ways and Means health portfolio for Congressman Erik Paulsen and managed the House Medical Device Caucus.



Ralph Hall

Principal, Leavitt Partners

Ralph Hall provides consulting services to clients in the areas of FDA statutes and regulations, regulatory strategy and compliance, as well as health care policy and legislation, and particularly the application of those regulatory systems to the emerging technologies, medical devices, diagnostics and the pharmaceutical industry. Ralph has extensive industry experience as he has previously served as counsel at Faegre Baker Daniels; general counsel for Guidant CRM and chief compliance officer for Guidant and held several roles in the legal department at Eli Lilly. As one of the nation's foremost experts in his field, Ralph also served as Professor of Practice at the University of Minnesota Law School and Carlson School of Management and now is a Lecturer at the University of Michigan Law School, where he teaches FDA law.



Ryan Howells

Principal, Leavitt Partners

Ryan Howells' expertise focuses on the intersection of digital health, interoperability, business strategy, and health care policy. He currently helps lead the CARIN Alliance, a multi-sector, public-private alliance focused on providing consumers with digital access to their health information. Ryan is a member of the CMS Medicaid Information Technology Architecture (MITA) Governance Board, Carequality Steering Committee, ONC's FAST Identity Tiger Team, and the VCI.org SMART Health Cards Steering Committee. He also serves as a board member or observer for multiple health care companies. Prior to Leavitt Partners, Ryan served in multiple executive roles for health care technology organizations, consulting organizations, and health plans.

Our Experts



Matt Hughes

Senior Director, Leavitt Partners

Matt Hughes advises health care coalitions and provides policy counsel and analysis involving regulations, legislation, and implications for health care stakeholders. Matt has experience in public policy, government relations, and membership recruitment and association management. Prior to joining Leavitt Partners, Matt was vice president & Minnesota managing director of Cooperative Network, a senior policy advisor to Minnesota Governor Tim Pawlenty, and a deputy assistant secretary for legislation at HHS. Matt also served as legislative assistant in the offices of Senator Mike Crapo of Idaho and former Congressman Mark Kennedy of Minnesota, in addition to working as a committee administrator and research consultant in the Minnesota House of Representatives.



Kevin Kirby

Managing Director, The Moran Company, an HMA Company

Kevin Kirby has more than 25 years of experience in Medicare reimbursement, with a focus on Medicare Part B. Kevin's work focuses on pharmaceutical, pharmacy and biotechnology policies, including Medicare reimbursement issues and policy and strategy development on various pieces of Medicare reform legislation. He was active in policy development for clients interested in issues that were affected by the Affordable Care Act and is an expert in a variety of drug reimbursement issues governed by the Medicare Modernization Act.



Anne Marie Lauterbach

Principal, Leavitt Partners

Anne Marie Lauterbach provides policy counsel and analysis to clients on coverage and reimbursement issues, including regulations, legislation, and business implications. Anne Marie's experience includes developing strategic messages and policy positions for Capitol Hill, administration, trade associations, and corporate audiences. Prior to joining Leavitt Partners, Anne Marie was a vice president for Faegre BD Consulting in the firm's health and biosciences group.

Our Experts



Dave Lee

Principal, Leavitt Partners

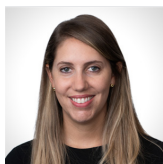
David Lee provides policy counsel and analysis to clients on issues related to government payers, including Medicare and Medicaid, health care reform, health IT, and other provider issues. Prior to joining Leavitt Partners, David served as director of regulatory affairs and policy for the National Rural Health Association where he directed advocacy efforts on Capitol Hill and with administrative agencies on issues related to rural health care. Before working at NRHA, David served on the staff of Senator Robert F. Bennett.



Tom McCaffery

Principal, HMA

Tom McCaffery has more than 25 years of experience in the health care industry, federal government, California state government, and not-for-profit sector. He was most recently the Assistant Secretary of Defense for Health Affairs, serving as the principal medical advisor to the Secretary of Defense. He administered the Military Health System's (MHS's) \$50 billion Defense Health Program (DHP) budget and was responsible for ensuring the global delivery of quality, cost effective health care to 9.4 million Service Members, retirees, and their families. Tom also served as Vice President, California State Partnerships at Blue Shield of California.



Laura Pence

Director, Leavitt Partners

Laura Pence advises complex health care coalitions and provides policy counsel and analysis involving regulations, legislation, and their implications for health care stakeholders. Laura brings strong expertise in public health and commercial insurance.

Prior to joining Leavitt Partners, Laura served at the U.S. Department of Health and Human Services (HHS) in several capacities, including Senior Advisor to the Secretary and Deputy Assistant Secretary for Legislation. In these roles, Laura served as an advisor to the secretary and liaison to Congress on public health and FDA issues. Laura was also a Health Policy Advisor to U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP) Chairman Lamar Alexander, where she helped lead Committee efforts on the bipartisan 21st Century Cures Act as well as landmark mental health and opioid legislation.

Our Experts



Melissa Pfaff

Director, Leavitt Partners

Melissa Pfaff provides policy guidance to clients on a range of public health issues and the federal authorizing, budget, and appropriations processes. Her work focuses on mental health and substance use disorders, public health preparedness and response, biomedical research, and other issues of public health importance.

Prior to joining Leavitt Partners, she served as Senior Health Policy Advisor on the Senate Health, Education, Labor, and Pensions (HELP) Committee under Ranking Member Mike Enzi, Chairman Lamar Alexander, and Ranking Member Richard Burr. Melissa worked with bipartisan member staff, agencies at the Department of Health and Human Services (HHS), and stakeholders on numerous legislative initiatives related to public health, advance biomedical research and innovation, and improve access to mental health and substance use disorder services.



Amy Comstock Rick

Principal, Leavitt Partners

Amy Comstock Rick leads the Medicines Development Modernization Initiative and advises on federal healthcare policy, FDA, NIH, drug development and research convenings, and patient engagement initiatives. Amy has over 30 years of experience leading organizations, executing strategy, building consensus, and advocating policies across constituencies. Prior to joining Leavitt Partners, she served as the President and Chief Executive Officer of the Food and Drug Law Institute.

Amy has also served as the CEO of the Parkinson's Action Network, President of the Coalition for the Advancement of Medical Research, on the NIH Institute for Neurological Disorders and Stroke's Advisory Council, and on the Boards of Directors of the National Health Council, Research!America, and the American Brain Coalition.

Our Experts



Mark Roberts

Director, Leavitt Partners

Mark Roberts is a director based in Washington, D.C., with Capitol Hill expertise and more than 8 years of consulting and project managing health care alliances and individual clients. He leads HL7 interactions for the CARIN Alliance and Leavitt Partners including the development and publication of three HL7 FHIR implementation guides: CARIN Blue Button, CARIN Digital Insurance Card, and Consumer Real-Time Pharmacy Benefit Check. Mark also provides federal policy research, analysis, and advocacy to clients and multi-sector alliances. His areas of focus include health information technology, interoperability, HL7 FHIR, FDA, and the Affordable Care Act.



Sarah Hudson Scholle

Principal, Leavitt Partners

At Leavitt Partners, Sarah Hudson Scholle specializes in supporting multi-sector alliances to promote improvement in quality, equity and person-centered healthcare. Before coming to Leavitt Partners, Sarah was Vice President of Research and Analysis at the National Committee for Quality Assurance (NCQA), where she led a portfolio of quantitative and qualitative research that contributed to national thought leadership in quality and equity, contributed to program development and policy action, and resulted in numerous peer-reviewed studies.

Sarah also led research underpinning NCQA's health equity accreditation program and supported CMS Office of Minority Health on contracts to identify disparities, develop methods for characterizing equity and identify opportunities for policy change.

Our Experts



Sara Singleton

Principal, Leavitt Partners

Sara Singleton acts as an advisor to the National Alliance to Impact the Social Determinants of Health (NASDOH), in addition to advising clients throughout the healthcare sector on federal healthcare policy issues including research and drug development, public health, and the Affordable Care Act. Prior to joining Leavitt Partners, Sara was a senior director of policy & advocacy at the Cystic Fibrosis Foundation; the deputy assistant secretary for legislation at the U.S. Department of Health and Human Services; policy advisor with the Senate Health, Education, Labor and Pensions (HELP) Committee under Chairman Tom Harkin, and a legislative assistant for Assistant Senate Majority Leader Richard Durbin.



Josh Trent

Managing Principal, Leavitt Partners

Josh Trent develops and manages complex, multi-sector alliances and advises clients throughout the health care sector on federal health care policy and strategy. Josh specializes in health care coverage and delivery system policy issues related to Medicare, Medicaid, and the Children's Health Insurance Program, the Affordable Care Act, private health insurance, and the 340B program. Josh previously served as chief health counsel for the Chairman of the Committee on Energy and Commerce, health policy advisor to a U.S. Senator, deputy director in the HHS Office of Refugee Resettlement, and deputy associate director in the White House Office of Presidential Personnel.



Elizabeth Wroe

Principal, Leavitt Partners

Liz Wroe advises clients on policy development and drafting, direct advocacy, and building and managing complex, multi-sector alliances. She has extensive subject matter expertise in Federal legislative, budget, and appropriations processes as well as commercial insurance, employer-sponsored health care, medical product regulation, and biodefense. Liz served as Chief Counsel and Director of Outreach and Coalitions for Chairman Lamar Alexander of the U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP), and Health Policy Director for Ranking Member Judd Gregg on the U.S. Senate Budget Committee. Liz has also led several policy-changing multi-sector alliance and advocacy strategies.



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