Cooley

Stephanie P. Hales

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Life Sciences and Healthcare Regulatory
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CooleyREG

Stephanie helps clients navigate complex healthcare legislative and regulatory developments, providing sharp analysis and strategic advocacy to stakeholders across the life sciences industry in connection with proposed and final policies, new product launches, market access issues, regulatory litigation and transactional matters. Drawing on her deep experience, Stephanie delivers pragmatic, sophisticated counsel to life sciences and healthcare clients, advising pharmaceutical, biotech, medical device, digital health and diagnostics companies, as well as healthcare providers, financial institutions and insurers. She regularly advises on high-stakes matters that arise in these sectors, including coverage and reimbursement, drug pricing, compliance, government agency and congressional investigations, and Administrative Procedure Act (APA) litigation.

Stephanie leverages her experience and insights to advise clients on issues and developments related to ongoing implementation of the Affordable Care Act (ACA), Inflation Reduction Act (IRA), and other key legislative and regulatory actions – including changes focused on Medicare, Medicaid and the 340B Drug Pricing Program (340B Program); developments related to market access, coverage, coding and reimbursement for innovative treatments and technologies; requirements for health information privacy, security and transparency; and policies affecting nondiscrimination, access to care and other compliance obligations under government healthcare programs and commercial plans.

Stephanie's representative matters have included:

- Strategic analysis and advocacy with federal agencies and Congress in connection with Medicare, Medicaid, 340B Program, ACA, and IRA issues, including high-stakes regulatory and legislative developments*
- Representation in connection with a broad range of Medicare national and local coverage determinations (NCDs and LCDs) focused on drugs, biologicals, medical devices, diagnostics, and other healthcare items and services, including:
  - Analyzing and preparing comments on proposed policies
  - Developing and advancing reconsideration requests and other advocacy strategies through engagement with the Centers for Medicare & Medicaid Services (CMS) and Medicare Administrative Contractors (MACs)
  - Challenging existing policies at the agency level and through litigation*
- Successful applications and related advocacy to secure key reimbursement and coding outcomes and

milestones, including:
    - New Technology Add-on Payments (NTAP) for innovative new products under the Medicare Hospital Inpatient Prospective Payment System
    - Pass-Through Payment Status for new drugs, biologicals and medical devices under the Medicare Hospital Outpatient Prospective Payment System
    - New and/or revised coding under the Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology (CPT), and ICD-10-CM and ICD-10-PCS code sets*
- Advice and counseling in connection with drug pricing issues, government price reporting considerations and requirements, CMS Innovation Center (Center for Medicare & Medicaid Innovation (CMMI)) models and proposals, and 340B Program compliance matters, advocacy strategy, policies and procedures, audits, legislative and regulatory developments, and litigation*
- Development of comments, presentations to federal and state agencies, and collaboration with other stakeholders on proposals and policies affecting coverage, reimbursement, coding, pricing and compliance issues under federal and state healthcare programs*
- Counseling on healthcare privacy and security issues, healthcare fraud and abuse laws, Sunshine Act requirements, and considerations in connection with developing and implementing patient assistance programs*
- Analysis and advice in connection with new product launches, pipeline development and potential transactions, including:
    - Risks and opportunities related to coverage, coding and payment
    - Pricing and price reporting considerations
    - Market access issues
    - Regulatory requirements for drugs, biologicals, medical devices, diagnostics, digital health technologies, and other healthcare items and services*

*Representation handled before joining Cooley

Stephanie also maintains an active pro bono practice, representing clients challenging Medicaid coverage and disability benefits denials, advocating on healthcare public policy issues, and seeking relief relating to criminal and social justice issues. During law school, she was an executive editor on the University of Pennsylvania Law Review and participated in the Custody & Support Assistance Clinic at Philadelphia Legal Assistance. After graduating from law school, Stephanie clerked for Judge Diane P. Wood of the US Court of Appeals for the Seventh Circuit. Additionally, she served as adjunct faculty at the University of Pennsylvania for a medical ethics and health policy course titled, “The Future of the American Health Care System: Health Policy and the Affordable Care Act.”

Education

University of Pennsylvania Carey Law School JD, cum laude, 2007

University of Pennsylvania Perelman School of Medicine MBE (Master of Biomedical Ethics), 2007

Washington University in St. Louis BA, English Literature, summa cum laude, Phi Beta Kappa, 2004

Admissions & Credentials

District of Columbia

Illinois

Court Admissions

US Supreme Court

US Court of Appeals for the Seventh Circuit

US District Court for the District of Columbia

Rankings & Accolades

District of Columbia Bar Association: Laura N. Rinaldi Pro Bono Lawyer of the Year award (2020)

Disability Rights Maryland: Legal Advocacy award (2019)

Autoimmune Association (formerly the American Autoimmune Related Diseases Association): “Autoimmune Hero” (2016)

Memberships & Affiliations

American Bar Association (ABA) Health Law Section and Administrative Law and Regulatory Practice Section, member

Whitman-Walker Health Clinic, board of directors, audit and compliance committee chair

Pathways to Housing DC, board of directors, governance committee chair

Children’s Law Center, board of directors

Volare (formerly Network for Victim Recovery of DC), board of directors

Autoimmune Association, advisor to the board of directors