Hogan Lovells

Brian Carey

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Biography

For over two decades, Brian Carey has advised life sciences and health care companies on complex regulatory and legislative health policy matters. He has extensive experience advising biopharma clients on complex Medicare coverage, payment, and compliance matters. Brian's experience advocating before the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, and U.S. Congress provides his clients with the confidence and insights to recognize regulatory risk and opportunities to promote adoption of new technologies.

Brian regularly advises innovative medical technology developers, medical trade associations, leading clinical laboratories, and molecular diagnostic companies through the evolving regulatory requirements to commercialize new technologies successfully. His practice focuses on addressing regulatory challenges for Laboratory Developed Tests, assessing payment under the Protecting Access to Medicare Act of 2014 (PAMA), and establishing coverage pathways with public and private payers.

Representative experience

Enabled a pharmaceutical to obtain the first Medicare New Technology Add on Payment (NTAP) for an oral therapy.*

Helped CMS design and create one of the first data registries in its CED program, by advising a coalition of leading academic medical centers and medical device

Practices

- Health
- Government Relations and Public Affairs
- Medical Device and Technology Regulatory
- Pharmaceuticals and Biotechnology Regulatory

Industries

- Life Sciences and Health Care

Areas of focus

- Health Legislation and Policy
- Medical Devices
- Pharmaceuticals and

manufacturers.*

Advised leading molecular diagnostic company on the development of the current Medicare coverage, payment, and coding challenges on the Clinical Laboratory Fee Schedule (CLFS).*

Developed novel legal arguments and assembled compelling scientific evidence that successfully reversed an adverse policy decision affecting the coding and payment for biotechnology product.*

Presented legal arguments for a new medical technology that led to the creation of a new DRG for an inpatient hospital payment.*

Represented a biotechnology client before CMS and Congress, leading to the creation of a new payment methodology for therapeutic radiopharmaceuticals based on the Average Sales Price methodology.*

Advised numerous clinical laboratories on the local coverage process with Medicare Administrative Contractors.*

*Matter handled prior to joining Hogan Lovells.

Awards and rankings

- America's Leading Lawyers for Business, *Chambers USA*, 2020-2024
- Massachusetts Supreme Judicial Court, *Pro Bono Honor Roll*, 2019

Latest thinking and events

- News
  - White House issues Executive Order directing efforts to lower drug prices
- News
  - CMS Proposes Guidance on Use of Real World Data for Coverage with Evidence Development
- News
  - JPM 2025 recap: Panelists discuss life sciences growth strategies, policy

Biotechnology

Education and admissions

Education

J.D., Boston College Law School, magna cum laude, 1997

B.S.E., Wharton School of Business, Philadelphia, 1992

B.A., University of Pennsylvania, 1992

Bar admissions and qualifications

Massachusetts

New York

District of Columbia

Court admissions

U.S. Court of Appeals, First Circuit

U.S. District Court, Southern District of New York

U.S. District Court, District of Massachusetts

uncertainties, and promising regulatory opportunities

- Hogan Lovells Events
  - Fireside chats with Hogan Lovells during JPM 2025
- Hogan Lovells Events
  - J.P. Morgan Healthcare Conference
- Hogan Lovells Events
  - Boston: Life Sciences and Health Care Horizons 2024