HLB HOOPER LUNDY BOOKMAN

SECTORS

CLINICAL LABORATORY

For clinical, molecular, and anatomic pathology laboratories across the country, Hooper, Lundy & Bookman provides comprehensive representation focused on facilitating their critical work. We recognize the unique place labs have in the continuum of care and the distinct regulatory, operational, and payment issues they face. Our counsel minimizes compliance risks while our advocacy protects and advances our clients' interests in reimbursement matters and across the full spectrum of government audits, investigations, enforcement actions, and other litigation.

While clinical laboratories continue to develop novel approaches and increasingly tailored and accurate diagnostic and molecular tests, the legal and business environments in which they operate are also evolving. Managed care, value-based, and other evolving payment arrangements present opportunities and potential risks. At the same time, government scrutiny and the costs and disruptions that can follow are ever-present concerns. HLB works with independent clinical laboratories, physician's office laboratories (POL), and hospital-operated labs on every day-to-day and long-range issue that intersects with the law.

Our experience serving clinical laboratories extends back decades, including representing the American Clinical Laboratory Association and the California Clinical Laboratory Association in many high-profile matters. HLB attorneys have played instrumental roles in some of the industry's most impactful cases, including establishing favorable state and federal court precedent on Medicare payment and coverage issues, alleged fraud and abuse, and other matters. We are recognized throughout the health care industry for our reimbursement practice and compliance capabilities, while a deep bench of litigators, transactional attorneys, and government relations and health care policy professionals complete the full suite of services we provide to clinical laboratories.

Our clinical laboratory representation includes:

Regulatory Compliance Counseling

- Medicare Conditions of Participation and Conditions for Coverage, including coverage of molecular and diagnostic testing and other lab-developed tests
- CLIA certification and compliance
- State licensure and compliance matters
- Institutional review board (IRB) compliance
- HIPAA, FDA, and Medicare reimbursement
- Fraud and abuse issues, including Stark Law and the federal anti-kickback statute
- Anti-markup issues
- Coronavirus Aid, Relief, and Economic Security (CARES) Act compliance

Medicare Audits, Investigations, Suspensions, and Claims Appeals, and Public and Private Payor Reimbursement Disputes

- Payor audits, including RAC, UPIC, MAC, Medicare, Medicaid, and private payor

- Other reimbursement matters involving the Clinical Lab Fee Schedule, Medicare Physician Fee Schedule, and Medicare Outpatient Prospective Payment System
- Medicare audit defense appeals
- Appeals of claim denials
- Medicare suspension investigations and rebuttals
- Medicare overpayment defense appeals
- Medicare post-payment review
- COVID-19 reimbursement issues, including cash price rules for COVID-19 tests and the payment of claims through the HRSA COVID-19 Uninsured Fund
- Managed care payment disputes
- Private payor reimbursement matters

Litigation

- Defense of False Claims Act, Stark Law, anti-kickback, fraud and abuse, and *qui tam* relator matters
- Criminal matters
- Antitrust matters
- Commercial litigation
- Payor litigation
- Medical necessity
- Marketing and labeling claims
- Managed care payment litigation

Operational, Transactional, and Policy Advocacy Matters

- Formation, structuring, licensing, financing, and billing
- Operations and corporate governance
- Provider agreements
- Ancillary agreements
- Mergers, acquisitions, joint ventures, affiliations, and other arrangements
- Clinical research contracts
- Managed care contracts
- Change of ownership

RELATED SERVICES

Antitrust and Unfair Business Practices

Compliance

COVID-19 / Public Health Emergencies

False Claims Act

Fraud and Abuse, Stark, Anti-Kickback Counseling and Defense

Government Investigations

Government Relations and Public Policy

Litigation, Mediation, Arbitration

Managed Care

Medicare, Medicaid, Other Governmental Reimbursement and Payment

Medicare and Medicaid Audits, Appeals, and Reimbursement Litigation

Payor-Provider Disputes

Provider and Supplier Operations

Value-Based Arrangements

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