

Laboratories

Working across every dimension in the laboratory space, Polsinelli attorneys advise a wide range of laboratories on broad range of legal and policy issues. Our laboratory clients are on the cutting edge of genetic and genomic testing, and we provide counsel on the coverage and reimbursement of a wide range of laboratory tests including laboratory developed tests. Attorneys in this specialized practice area also advise on regulatory issues such as payment under the Clinical Lab Fee Schedule and compliance with reporting obligations under the Protecting Access to Medicare Act of 2014 (PAMA) and structuring of joint ventures and strategic partnership arrangements with a wide range of providers.

Often combining the experience of our health law and public policy teams and a full host of attorneys that support transactional, tax, intellectual property and benefits work in the laboratory space, Polsinelli advises both laboratories and private equity in every aspect of the life cycle of a laboratory, including Clinical Laboratory Improvement Amendments (CLIA) regulations and state certification, Medicare and commercial payor coverage and reimbursement, pricing, data reporting, coding and issues related to molecular diagnostics and other clinical laboratory tests. We understand the laboratory business. We understand your challenges and opportunities in a rapidly evolving marketplace even more dramatically evolving by responding to COVID-19 testing needs and supply chain issues.

The scope of our focused laboratory practice includes many key services:

Regulatory Counsel, Compliance & Litigation Defense

Our work includes application and analysis of a myriad of federal laws as applied in the laboratory space, from specific applications of the Federal Anti-Kickback Statute, the federal Physician Self-Referral Law (commonly known as the Stark Law), the Federal Civil False Claims Act, CLIA, state certification and licensure issues, and other state laws that impact laboratory/physician relationships including direct billing requirements or other payment limitations.

Our experienced team assists with audits and investigations, including audits by Medicare contractors, state Medicaid agencies and increasingly aggressive commercial payors, including Medicare or Medicaid managed care organizations. Several of our attorneys joined the firm enforcement and regulatory agencies – including the Centers for Medicare and Medicaid Services (CMS), the Department of Justice and the Office of Civil Rights. Our team handles both civil and criminal enforcement matters across the United States. Our team members bring a unique understanding of the perspective and goals of law enforcement agencies and include seasoned litigators with direct experience in a wide range of commercial payor disputes including contracting, recoupment and payment matters.

Focused Transactional Practice

Polsinelli's corporate and transactional team has experience in the acquisition and sale of laboratories and structuring of joint ventures to conform to regulatory requirements. This includes private equity investment in or

sale of laboratories, joint venture transactions with hospitals and health care systems, permissible contractual and marketing arrangements, and custom tailored due diligence solutions and project management to support our team of experienced corporate and regulatory attorneys.

Policy & Advocacy

Our work in this area includes advocacy before Congress, the Centers for Medicare & Medicaid Services (CMS), Medicare contractors, state Medicaid programs and commercial insurers on a wide range of issues including coding, coverage, and payment and other guidelines related to diagnostic laboratory services, including advanced diagnostic services such as new methods of testing and molecular diagnostic testing services. In addition, as new testing issues implicate guidance from the Federal Drug Administration (FDA), our robust FDA practice counsels on issues related to laboratory testing equipment, testing methodologies, advertising and promotion.

Strategic Growth Plans

We work with a wide range of laboratories as they evaluate opportunities to expand 'traditional' testing into expanded practice options, such as physician alignment opportunities. We support clinical trials by and between a wide range of health care providers and the pharmaceutical industry. Our national experience in the telehealth and remote patient monitoring space naturally plugs into our laboratory clients as they explore new opportunities for integrated care and home-based services. Our team has experience developing marketing strategies that address regulatory constraints and yet, opportunities for growth.