

OUR PRACTICE

Clinical Laboratories

The attorneys in Baker Donelson's Health Law Department provide comprehensive representation to clinical, anatomic pathology and molecular laboratories throughout the United States, with a guiding philosophy of helping clients avoid problems by understanding and complying with state and federal laws and regulations. We handle a full range of routine and complex legal matters, including the establishment and licensing of new labs, compliance with laws such as the Clinical Laboratory Improvement Amendments (CLIA) and many other federal regulations, negotiating provider agreements, problems with billing and coding, and handling subpoenas and investigations arising from the False Claims Act, the Anti-Kickback Statute and the Stark law. Our Washington, D.C.-based Health Care Policy Group also represents our lab clients' interests on a policymaking level.

We regularly work with clients on complex billing matters and on requisition form development, as well as direct to patient results, ABN development, compliance with state laboratory rules impacting certain business practices, direct billing requirements, shell lab issues, structuring relationships with laboratories, laboratory information systems, EHR issues and a variety of business models and operational issues.

For labs, business is both growing and evolving, as medical researchers refine existing tests and develop new ones, including genetic analyses that hold the potential for transforming medicine. Many of the Baker Donelson attorneys who represent laboratories have a background in science, allowing us to understand and keep pace with developments that will have a profound impact on the industry and molecular laboratories in particular.

For labs that violate federal and state rules, the stakes are high. Under the False Claims Act, the federal government can recover payments dating back seven years – ten if intentional fraud is alleged. Historically, scrutiny of labs has been tight. More than 20 years ago, clinical labs were the first service covered by the Stark law.

Clinical, anatomic pathology and molecular laboratories face complicated, nuanced legal challenges on an almost daily basis. And important legal issues are in flux. The attorneys in Baker Donelson's Health Law Department have the business, science and legal knowledge to help labs address those challenges.