ALSTON & BIRD

Peter M. Kazon

Senior Counsel

202.239.3334
peter.kazon@alston.com
Washington, D.C. | The Atlantic Building, 950 F Street, NW | Washington, DC 20004-1404

Peter Kazon has more than 25 years of experience assisting companies and individuals in negotiating the complex legal and regulatory issues that health care providers routinely face. He counsels providers on matters involving Medicare coverage, reimbursement, billing, fraud and abuse and Stark self-referral issues. His primary practice areas include advising clinical laboratories and diagnostic companies on regulatory and compliance matters and assisting companies with emerging medical technologies with coverage, coding and reimbursement issues. Peter assists companies on compliance with the Federal Food, Drug, and Cosmetic Act and its recent amendments, with particular attention to FDA actions affecting in vitro diagnostic products.

Peter is a frequent speaker and writer on health care issues and sits on the editorial advisory board of Bloomberg *BNA's Medical Devices Law & Industry Report*. His recent speeches have addressed a variety of topics, including Medicare medical necessity requirements, regulatory requirements applicable to genetic tests, new federal requirements applicable to the provision of electronic medical record technology and Medicare reimbursement issues. Peter has been recognized as one of *The Best Lawyers in America©*.

Representative Experience

- Serves as outside counsel to an industry association that represents the major providers of clinical laboratory services, working on a wide variety of topic areas: helped draft comments on key CMS and OIG regulations, including proposals on physician self-referrals, "substantially in excess" provisions, reassignment and physician fee schedule requirements; helped develop strategy and responses for FDA initiatives related to Analyte Specific Reagents, IVDMIAs and other issues; has been involved on issues related to the implementation of CMS's proposed competitive bidding program for clinical laboratories and was involved in advising on the legislation that established a negotiated rulemaking procedure for laboratories; and advised the association in the negotiated rulemaking proceedings.
- Assisted a major manufacturer of a medical device used in bariatric (weight reduction) surgery in obtaining a National Coverage Decision from Medicare for its product.
- Assisted several diagnostic companies on due diligence in connection with planned acquisitions of other companies.
- Advised a supplier of a wound care technology on billing, coding and reimbursement issues related to its product.
- Counsels a major provider of anatomic pathology services on Medicare regulatory and compliance issues.

Publications & Presentations

Publications

- "Changing Time for Clinical Laboratories," *Bloomberg BNA Medical Devices Law & Industry Report*, April 27, 2016.

- "CMS Proposal for Clinical Laboratory Fee Schedule Overhaul Raises Questions," *Bloomberg BNA Medical Devices Law & Industry Report*, October 14, 2015.
- "FDA Announces Plans to Regulate Laboratory Developed Tests," *Bloomberg BNA Medical Devices Law & Industry Report*, August 20, 2014.
- "Medicare Reimbursement for Clinical Laboratory Tests Enters New Waters," *Bloomberg BNA Medical Devices Law & Industry Report*, January 22, 2014.

Professional & Community Engagement

- American Health Lawyers Association
- American Bar Association

Education

- Temple University (J.D., 1978)
- Tufts University (B.A., 1975)

Admitted to Practice

- District of Columbia
- Massachusetts

Related Services

Health Care | Corporate & Finance | Legislative & Public Policy | Health Care Regulatory Counseling and Fraud & Abuse | Health Care Legislative & Public Policy | FDA/Food, Drug & Device | Reimbursement | Corporate Compliance Programs