



## Robert E. Mazer

Senior Counsel

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Mr. Mazer advises health care providers on a broad range of payment and compliance issues, including Medicare, Medicaid and other third-party payment rules, the Federal Anti-kickback Statute, the Eliminating Kickbacks in Recovery Act (EKRA), the Stark Law, and the Clinical Laboratory Improvement Amendments of 1988 (CLIA). He also represents clients with related disputes with government agencies, CMS contractors and private insurers.

Mr. Mazer has extensive experience with legal, regulatory and business issues related to clinical laboratory and anatomic pathology services, including genomic testing such as pharmacogenetic tests. He assists clients with billing, discount and pricing issues, medical necessity and related documentation requirements, lab-to-lab referrals and reference lab agreements, the 70/30 or shell lab rule, issues raised by out-of-network status, including waiver of coinsurance or copayments and deductibles, TC/PC billing, laboratory director contracts, and management contracts, leases and other financial arrangements with physicians, hospitals and other referral sources. He also defends companies facing government investigations and those who are parties to regulatory or payment disputes, including recoupment actions based on medical necessity determinations or other payment requirements and CLIA sanctions. Mr. Mazer is experienced in assisting laboratories in responding to survey determinations of condition-level deficiencies under CLIA, such as findings related to impermissible proficiency testing (PT) referrals and has pursued administrative appeals on their behalf when necessary. He has successfully defended CLIA revocation actions, including those based on allegations of improper referrals of PT samples.

Mr. Mazer has significant experience before the Provider Reimbursement Review Board (PRRB) and in related federal court actions. His financial background, including prior service on the AICPA committee that develops the Audit and Accounting Guide for Health Care Organizations, provides Mr. Mazer with a substantial knowledge base regarding accounting principles, cost computations and fair market value determinations.

Mr. Mazer has co-authored compliance manuals related to Medicare fraud and abuse prohibitions, generally, and the Stark Law, specifically. He has also contributed chapters on legal issues related to clinical laboratory testing and on CLIA, and coding and payment principles applicable to laboratory and pathology services.

A frequent lecturer and author, Mr. Mazer has spoken at conferences sponsored by the American Institute of CPAs, Clinical Laboratory Management Association, American Health Law Association, Health Care Compliance Association (HCCA), and Washington G-2 Reports. Mr. Mazer served as the coordinator of the Laboratory Immersion Session for HCCA's Compliance Institute sponsored by the Health Care Compliance Association and addressed clinical laboratory issues at the 2019 Compliance Institute. He is also manager of the Laboratory Legislation Regulation group on LinkedIn.

Mr. Mazer serves on the adjunct faculty at the University of Maryland Carey School of Law teaching Health Care Business Arrangements.



## Professional Honors & Activities

### Professional Memberships

- Member – American Bar Association
- Member – [American Health Law Association](#)
- Member – [American Institute of Certified Public Accountants](#) (1996 – 2021)
  - Health Care Committee (1996 – 1999)
    - Chair, Task Force on Health Compliance and Reporting Issues (1997 – 1999)
    - Revision Task Force, Health Care Organizations Audit and Accounting Guide (2003)
- Member – Maryland State Bar Association

### Honoraries

- Listed in *The Best Lawyers in America*® for Health Care Law (2021 – 2025)
- AV® Preeminent™ Peer Review Rated by Martindale-Hubbell



## Publications

- "Federal Court Vacates LDT Final Rule" (April 2025)

### Journal Publications

- "Clinical Laboratory Compliance Issues, Part 2," *Journal of Health Care Compliance* (November – December 2018)
- "Clinical Laboratory Compliance Issues, Part 1," *Journal of Health Care Compliance* (September – October 2018)

### LinkedIn Publications

- "False Claims Act Settlement Underscores Laboratories' Risk Related to Physician's Use of Test Results," LinkedIn (November 2024)
- "Laboratory's Disclosure of Patient's Financial Responsibility May Be Insufficient to Satisfy State Consumer Protection Laws," LinkedIn (April 2024)
- "CLIA Requirements Related To Laboratory Director Responsibilities Specified Minimum On-site Visit Requirement May Have Opposite Intended Effect," LinkedIn (January 2024)
- "Sale and Purchase of Pathology Technical Component Arrangement May Violate Anti-kickback Statute," LinkedIn (October 2023)
- "Laboratory's Disclosure of Patient's Anticipated Financial Responsibility for Insurance-Covered Test Only Did Not Violate Consumer Protection Laws," LinkedIn (July 2023)
- "Lab Director's Lawsuit Fails to Prevent Two-Year CLIA Ban on Directing a Clinical Lab," LinkedIn (July 2022)
- "Court Holds that Labs' Payments for Marketing Physicians' Test Referrals May Violate EKRA," LinkedIn (June 2022)
- "OIG Declines to Approve Lab's Purchase of Specimen Collection Procedures from Hospital," LinkedIn (May 2022)
- "U.S. Court: Providers of COVID tests may pursue insurers for payment of COVID tests under ERISA plan," LinkedIn (March 2021)
- "Courts Reach Different Conclusions Whether CLIA Violations Violate False Claims Act," LinkedIn (January 2022)
- "U.S. District Court Finds EKRA Permits Commission Payments by Clinical Laboratories," LinkedIn (December 2021)
- "Insurance Company May Be Held to Promise to Cover Clinical Laboratory Tests," LinkedIn (September 2021)
- "Recent CLIA Decisions Demonstrate Importance of Pre-Appeal Corrective Actions," LinkedIn (May 2021)
- "Procedures to Avoid Medicare Payment Limitations May Not Violate False Claims Act," LinkedIn (April 2021)

- "Court Upholds Jury Determination That Commission-Based Payments Violate Anti-Kickback Statute," LinkedIn (February 2021)
- "Federal Court: Physicians Participating in Lab Kickback Arrangements May Violate False Claims Act," LinkedIn (February 2021)
- "CMS: Physician signature required to support claims for lab tests," LinkedIn (January 2021)
- "Government Attorneys Green Light Medicare Contractors to Deny Claims Using LCDs Developed Without Notice and Comment," LinkedIn (December 2020)
- "Labs May Have Legal Claim Against Insurers for Use of Unfair Tactics to Avoid Paying for Tests," LinkedIn (October 2020)
- "CLIA Sanctions Imposed For Violations Related to Tests That Labs Did Not Perform or Report Results," LinkedIn (September 2020)
- "Court Finds CLIA Violations Can Lead To False Claims Act Liability," LinkedIn (August 2020)
- "ALJ Finds That Innocent Billing Mistake Did Not Justify Enrollment Revocation," LinkedIn article (January 2020)
- "Pass-Through Billing Arrangement Leads To Litigation Between Participants," LinkedIn article (December 2019)
- "Reference Test Billing Arrangements Continue To Confound Clinical Laboratories," LinkedIn article (November 2019)
- "Federal Court Disregards LCD Requiring Denial of Genetic Test Claims," LinkedIn article (November 2019)
- "Federal Court Reviews Claims Based On Patient Billing Procedures For Clinical Laboratory Tests," LinkedIn article (August 2019)
- "Hospital Pays False Claims Act Penalty for Violating Medicare Outpatient Packaging Rules," LinkedIn article (July 2019)
- "United States Asserts That Physician Discounts/Client-Bill Arrangement Violate Anti-Kickback Statute and False Claims Act," LinkedIn article (June 2019)
- "Recent Court Decision Reflects Kickback Risks to Laboratories and Related Companies," LinkedIn article (May 2019)
- "Genetic Testing Company's Billing and Coding Practices Held to be Inadequate Basis for Securities Fraud Claims," LinkedIn article (April 2019)
- "Courts Disagree Whether Clinical Labs May Be Liable To Tested Employee For Erroneous Drug Testing Results," LinkedIn article (March 2019)
- "CMS Requires Signed Documentation of Specific Tests Ordered," LinkedIn article (December 2018)
- "Physician's Failure to Provide Medicare Contractor With Test Orders Forfeits Medicare Billing Privileges," LinkedIn article (December 2018)
- "New Federal Law Prohibits Kickback Arrangements Involving Laboratory Services Paid Under Private Insurance Plans," LinkedIn article (November 2018)
- "CMS Instructs Contractors to Deny Claims for Tests Without Signed Orders and Medical Necessity Documentation," LinkedIn article (November 2018)
- "Failure to Disclose Extreme Testing Delay on Payment Claims Results in Health Care Fraud Convictions," LinkedIn article (September 2018)
- "Clinical Laboratory Compliance - Payment For Referrals Of Private Business Can Violate Federal Anti-Kickback Statute," LinkedIn article (July 2018)
- "Laboratory Compliance - Sufficient Documentation of Medicare Contractor or Attorney Advice Required to Defend False Claims Act Charge," LinkedIn article (June 2018)
- "Laboratory Compliance - Intent to Comply Insufficient to Avoid Medicare Enrollment Revocation," LinkedIn article (May 2018)
- "Medicare Provider May Seek Injunction To Halt Collection Of Overpayments," LinkedIn article (April 2018)

- "CLIA Compliance—Lab Director's Passive Behavior Leads to Immediate Suspension of CLIA Certificate," LinkedIn article (February 2018)
- "Government Can Collect Medicare Overpayments from Laboratory's Owner-President," LinkedIn article (January 2018)
- "Independent Labs Can Rely on Referring Physician's Medical Necessity Determination for False Claims Act Purposes," LinkedIn article (December 2017)
- "Laboratory Owner Convicted Based On Medically Unnecessary Tests She Required," LinkedIn article (November 2017)
- "CMS Approves Enhanced Electronic Test Reports," LinkedIn article (October 2017)
- "Pass-Through Laboratory Arrangements Come Under Fire," LinkedIn article (September 2017)
- "Accurate Payment Claim Can Violate False Claim Act When Lab Test Is Not Medically Necessary," LinkedIn article (June 2017)
- "Direct Billing for Lab Tests for Hospital Patients Can Lead Directly to Trouble," LinkedIn article (May 2017)
- "Medical Necessity Requirement Bites Anatomic Pathologists," LinkedIn article (May 2017)
- "Waiver of Co-Payments and Deductibles for Private Pay Patients Can Be Federal Crime; Marketing Firm Potentially Liable," LinkedIn article (April 2017)

#### Other Publications

- "Lab Owners Beware – Conflicting EKRA Opinions Muddy the Landscape on Payments for Physicians' Test Referrals," republished in *Westlaw* (June 2022)
- "U.S. District Court Finds EKRA Permits Commission Payments," republished March 21, 2022, in *Westlaw* (December 2021)



#### Speaking Engagements

- "Payment Disputes with Commercial Insurers for COVID And Other Testing Services," G2 Intelligence Lab Institute Webinar (November 2022)
- "Private Payer Trends in the Handling and Payment of Lab Test Claims: EKRA, CURES Act Payment Issues, Waiver of Coinsurance, Medical Necessity, and More," Executive War College Conference on Laboratory & Pathology Management, New Orleans, Louisiana (April 2022)
- "Lab Testing During the COVID Pandemic," HCCA's 25th Annual Compliance Institute (April 22, 2021)
- "Recent and Emerging Issues Related to Clinical Laboratory Testing and How to Avoid Them," HCCA Compliance Institute (April 2019)
- "Recent and Emerging Issues Related to Clinical Lab," G-2 Lab Leadership Summit (March 2019)
- "Eliminating Kickbacks in Recovery Act (EKRA)," HCCA Webinar (March 2019)
- "Laboratory Compliance: Maintaining Compliance in an Uncertain and Changing Environment," HCCA Compliance Institute, Las Vegas, Nevada (April 2018)
- Co-presenter – "Laboratory Compliance: Keys to Successfully Navigating Regulatory Minefields," HCCA Web Conference (April 2018)
- "Compliance: Key Trends and Potential Vulnerabilities," Lab Institute 2017, G2 Intelligence (October 2017)
- "Laboratory Compliance: Maintaining Compliance in an Uncertain and Changing Environment," Compliance Institute, Health Care Compliance Association (March 2017)



#### Education

- University of Maryland School of Law, J.D.  
– *Maryland Law Review*, Research Editor
- University of Maryland, B.S.



## Admissions

- Maryland
- U.S. Court of Appeals for the District of Columbia Circuit
- U.S. Court of Appeals for the Federal Circuit
- U.S. Court of Federal Claims
- U.S. Court of Appeals for the Third Circuit
- U.S. Court of Appeals for the Fourth Circuit
- U.S. Court of Appeals for the Sixth Circuit
- U.S. Court of Appeals for the Seventh Circuit
- U.S. Court of Appeals for the Tenth Circuit