



Elizabeth Sullivan

**Member; Co-Chair, National Healthcare Practice Group
Cleveland**

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Practice Focus

- Healthcare
- Laboratories
- Regulatory investigations and government response
- Business counseling

Liz is co-chair of the firm's National Healthcare Practice. She began her legal career in the Healthcare Practice group at McDonald Hopkins and later served as an attorney in the legal department at The Cleveland Clinic Foundation before returning to McDonald Hopkins as a member.

While at the Cleveland Clinic, Liz provided regulatory advice and transactional guidance to various service lines, including the clinical laboratory, professional pathology, imaging, transplant, and remote and distance health teams. Over the course of her career, Liz has assisted various types of healthcare providers, including clinical laboratories, hospitals, physician specialty groups, telehealth providers, transplant centers, and surgery centers.

Liz has experience providing regulatory, licensing, compliance, reimbursement, contractual, and corporate guidance to clients. She has advised clients on state professional licensure laws, CLIA standards, state laboratory laws, government and private payor reimbursement policies and billing rules, federal and state fraud and abuse rules and regulations, state telehealth laws, and HIPAA rules and regulations. She has provided assistance to entities during licensure and accreditation surveys, government investigations, and through payor audits and disputes.

In addition to providing regulatory guidance to clients, Liz is also knowledgeable in evaluating how a business opportunity or arrangement implicates a provider's unique regulatory framework. Liz has counseled clients not only on the regulatory aspects of an arrangement as described above, but she is also experienced in reviewing and negotiating relevant contractual and legal documentation in connection with contemplated business arrangements.

Liz earned a J.D. and Certificate of Advanced Studies in Health Law from the University of Pittsburgh School of Law, an M.A. in Bioethics and a B.A., cum laude, in Political Science from Case Western Reserve University.

Admissions - State

- Ohio

Education

- University of Pittsburgh School of Law
- Case Western Reserve University

Honors and Awards

- Selected for Crain's Cleveland *Notable Women in Law* (2018)
- Selected for Crain's Cleveland *Notable Women in Healthcare* (2018)

Professional Membership

- Easterseals of Northern Ohio, Board Member

Alerts

- CMS is issuing enrollment revocations with 10-year enrollment bars under 2019 Final Rule
- CMS audits to resume August 3
- OIG Work Plan updated to include trend analysis to determine fraud and abuse in COVID-19 add on testing and review of expanded telehealth services
- Congress passes \$484B coronavirus relief bill
- ODH order for non-congregate sheltering: Protecting against liability while joining the battle against COVID-19
- CMS issues CLIA guidance during COVID-19 public health emergency
- CARES Act: An early analysis of the historic Coronavirus Aid, Relief and Economic Security Act
- CARES Act: Provisions designed to aid healthcare providers in response to COVID-19
- OIG issues policy statement and fact sheet on COVID-19 telehealth cost sharing waivers
- EKRA enforcement after a year of uncertainty
- Are you considering selling your dermatology practice?
- OIG focusing on laboratories involved in genetic testing scams
- UPDATE: Texas District Court issues preliminary injunction preventing CMS from recouping overpayments until an ALJ has heard and rendered a decision
- Texas District Court issues temporary injunction preventing CMS from recouping overpayments
- Federal and commercial payor medical record requests are important – Don't dismiss them!
- Medicare claims for outpatient physical therapy services often fail to comply with requirements
- CMS finalizes coverage for Next Generation Sequencing tests for patients with advanced cancer
- 2018 update on maximum charges for copies of medical records in Ohio
- New OIG report recommends Medicare contractors recover more than \$66M in improper payments
- CMS's Targeted Probe and Educate ("TPE") Program – Get Counsel Involved Early!
- UPDATE: Labs may rely on ordering physician's determination that a test is medically necessary
- New Ohio opioid prescription limits for acute pain take effect tomorrow
- Labs have independent duty to certify tests billed to Medicare are medically necessary
- FDA approves first digital pathology system for primary diagnosis
- College of American Pathologists to develop Pathologist Quality Registry

- What health care providers need to know about the American Health Care Act
- 2017 update on maximum charges for copies of medical records in Ohio

Blog Posts

- FDA discontinues Emergency Use Authorization reviews for laboratory developed tests
- HHS notice on provider relief fund reporting requirements
- HHS extends deadline to accept or reject CARES Act Provider Relief Funds
- CMS increases Medicare payment for COVID-19 lab tests using high-production equipment
- UPDATE: CMS reevaluates Accelerated Payment Program, suspends Advance Payment Program for Part B suppliers and points providers to relief fund
- FDA authorizes first at-home COVID-19 test
- CMS expands accelerated and advanced payments to offer additional financial relief for providers during the COVID-19 emergency period
- CMS issues guidance on payments for state medicaid telehealth services provided during COVID-19 pandemic
- OCR announces penalty waivers for telehealth COVID-19 emergency and other treatment
- CMS updates regarding coronavirus lab tests
- CMS completely revamps Medicaid Program Integrity Manual
- Medicare enrollment can be denied due to outstanding overpayments
- 3 federal fraud and abuse laws explained

News

- Liz Sullivan Named Notable Women in Healthcare 2018
- MH Business Exchange Episode 12 helps healthcare providers prepare and avoid payor audits
- Contini, Sullivan named co-chairs at McDonald Hopkins
- "Marijuana In Patient Care – Nine Model Guidelines From The Federation of State Medical Boards"
- "GOP Efforts to Repeal and Replace the Affordable Care Act - What Can Healthcare Providers Anticipate Moving Forward?"
- Healthcare Attorney Elizabeth Sullivan Joins the Cleveland Office of McDonald Hopkins

Podcasts

- Episode 12: Overpayment: Managing medical records requests and avoiding payor audits

External Publications

- Coauthor, "The American Health Care Act (AHCA), GOP Efforts to Repeal and Replace the Affordable Care Act – What Can Healthcare Providers Anticipate Moving Forward?", The Academy of Medicine of Cleveland & Northern Ohio, May/June 2017
- "Legal Considerations for Pathology and Laboratory Providers", American Society for Clinical Pathology, Lab Medicine Podcast Series, March 1, 2017
- "Patient Privacy Breach Attracts National News Coverage," The Dark Report, December 19, 2016

Events

- Restarting Healthcare: Readiness, Risk and Response | Thursday, May 21, 2020
- Legal, Regulatory & Compliance Direct to Consumer Conversation | Thursday, February 27, 2020
- What Lab Leaders Need to Know to Prepare for 2020: Bracing for Aggressive Payor Audits, Rigid Enforcement of Fraud and Abuse Laws, and More | Wednesday, November 20, 2019
- Clinical Laboratories and Payer Scrutiny: Increased Audits, Recoupment Actions, Litigation | Tuesday, October 1, 2019
- Eliminating Kickbacks in Recovery Act Webinar | Tuesday, August 20, 2019
- Eliminating Kickbacks in Recovery Act (EKRA) and the impact on the healthcare industry | Thursday, April 11, 2019
- Is Your Hospital at Risk? | Tuesday, July 10, 2018
- American Pathology Foundation | Monday, April 16, 2018
- Clinical Laboratories and Payer Scrutiny | Wednesday, February 7, 2018

Speaking Engagements

- “Anatomy of a Successful Clinical Lab or Molecular/Genetic Lab Transaction in the Time of the Pandemic: The Advisers’ View”, Livestream Workshop - 2020 Virtual Executive War College, September 1, 2020.
- Co-presenter, "Successfully Navigating through COVID-19", Florida Medical Association Webinar, May 1, 2020.
- Co-presenter, "How to Successfully Lead Your Lab Through the Legislative and Regulatory Landscape of COVID-19", The Dark Report Webinar, April 22, 2020.
- Co-presenter, “What Lab Leaders Need to Know to Prepare for 2020: Bracing for Aggressive Payor Audits, Rigid Enforcement of Fraud and Abuse, and More”, The Dark Report Webinar, November 20, 2019
- Co-presenter, "Clinical Laboratories and Payer Scrutiny: Increased Audits, Recoupment Actions, Litigation," Strafford Webinar, October 1, 2019
- Co-presenter, “Legal Landmines in Professional and Executive Employment: A Practical Discussion of Essential Contract Terms”, American Society for Clinical Pathology 2019 Annual Meeting, Phoenix, Arizona, September 12, 2019
- "Compliance and Regulatory Issues Associated with the PAMA Statute and the CMS Final Rule for Reporting Private Payer Lab Test Prices: Risks, Consequences, and Often-Overlooked Requirements”, The Executive War College, New Orleans, Louisiana, May 2, 2019
- Panel Moderator, “Anatomic Pathology Groups and Their Labs: Effective Strategies for Maintaining Clinical Excellence and Financial Stability during Disruptive Times”, The Executive War College, New Orleans, Louisiana, April 30, 2019
- "Your Practice and the Federal Stark, Anti-Kickback and Anti-Markup Rule: From TC/PC to Hospital Relationships”, American Pathology Foundation Coding & Practice Management, New Orleans, Louisiana, April 15, 2019
- Co-presenter, "Payor Audits: Preparing Your Lab”, Cardinal Health Lab Briefings Webinar, February 27, 2019
- Co-presenter, “HIPAA Update for the Pathology Practice”, American Pathology Foundation Webinars,

November 1, 2018

- Co-presenter, “Defending Against Payor Audits – Record Requests Through the Appeals Process”, G2 Intelligence - Lab Compliance Essentials 2018, Chicago, Illinois, June 8, 2018
- “Another Year of Legislative and Regulatory Uncertainty?”, American Pathology Foundation Coding & Practice Management, New Orleans, Louisiana, April 16, 2018
- Copresenter, "Clinical Laboratories and Payer Scrutiny: Increased Audits, Recoupment Actions, Litigation," Strafford Webinar, February 7, 2018
- “The Lawyer's Perspective on the Molecular/Genetic Testing Landscape: Priority Issues Involving Managed Care Contracting, Payor Audits, Compliance, Sales Practices, and Fraudulent Marketing Schemes”, The Executive War College, New Orleans, Louisiana, May 4, 2017
- "The First 100 Days of the New Administration: What We Know and What We Don't", American Pathology Foundation Coding & Practice Management, Atlanta, Georgia, March 27, 2017
- Copresenter, "Pathology Compliance: Strategies for Success in 2017", American Pathology Foundation Coding & Practice Management, Atlanta, Georgia, March 27, 2017
- "Compliance Considerations for Clinical Laboratories”, Cardinal Health Lab Briefings Webinar Series, January 25, 2017
- Copresenter, “Preparing For 2017's Tougher Lab Regulations and New Legal Issues: What Every Lab and Pathology Group Needs to Know to Protect Revenue and Stay Compliant”, The Dark Report Webinar, October 12, 2016