



→ Erica J. Kraus

Partner

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Erica Kraus is a partner in the Corporate Practice Group in the firm's Washington, D.C. office.

Areas of Practice

Erica represents healthcare entities in regulatory compliance matters. She advises clients on reaching their goals in compliance with federal and state fraud and abuse laws, assists clients in responding to government investigations, and represents clients in False Claims Act litigation. Erica also assists clients with regulatory due diligence in transactional matters, and through advocacy with federal and state regulators, and leverages her background in health policy to help clients maximize opportunities in the changing healthcare landscape. Representative matters include:

- Assisting in internal investigations of reported potential regulatory non-compliance
- Responding to government Civil Investigative Demands
- Representing defendants in False Claims Act litigation
- Advising clients in preparation for and during transactions in evaluating regulatory compliance and making related strategic decisions
- Advising clients on compliance with the Civil Monetary Penalties Law, Stark Law, and Anti-Kickback Statute
- Drafting and submitting self-disclosures through CMS' Self-Referral Disclosure Protocol
- Assisting clients with CMS Innovation Center model participation and compliance with applicable waivers
- Assisting clients in developing value-based compensation and support strategies and care coordination initiatives in compliance with applicable laws
- Advising clients on HCC strategy and compliance
- Preparing CMS Hearing Officer appeals of Medicare Advantage and Prescription Drug Plan application denials
- Appealing Medicare Administrative Contractor claim denials
- Advising clients on the implications of drug pricing reform
- Preparing filings with the Provider Reimbursement Review Board
- Advising clients on regulatory waivers and compliance during the COVID-19 pandemic
- Advising clients on the evolving MACRA implementation landscape and transition toward value-based care

Prior to joining the firm, Erica acted as a Perspective Reports intern for the *New England Journal of Medicine*, where she reviewed and summarized health law and policy news, and worked as an intern for the U.S. Department of Health and Human Services, focusing particularly on employment law projects, including preparing for EEOC, MSPB and federal district court litigation. Erica currently serves as an Adjunct Professorial Lecturer at American University's Washington College of Law, teaching on the False Claims Act in the Healthcare Industry.

Honors

Up and Comer, Healthcare - District of Columbia, *Chambers USA*, 2022-2023

Ones to Watch – Healthcare Law, *Best Lawyers*, 2021-2024

Recommended Lawyer: Healthcare, *Legal 500*, 2023

Articles

- 2024 Top-of-Mind Issues for Life Sciences Companies
01.25.2024
- Third Time's a Charm: The Supremes Will Finally Settle the Rule 9(b) False Claims Act Circuit Split
Texas Lawyer, 07.08.2022
- Co-author with K. Kung, "New FDA Rules Are Boon to Medical Mobile App Developers," *Law360*, August 7, 2014
- "A Shift on 'Pay for Delay' – Reopening Doors for Pharmaceutical Competition?" *New England Journal of Medicine*, November 1, 2012

False Claims Act Defense Blog Posts

- "The Government's Take on Materiality After Escobar," September 15, 2016

FDA Blog Posts

- "2024 Top-of-Mind Issues for Life Sciences Companies," January 25, 2024

Healthcare Law Blog Posts

- "Increased Scrutiny into Agents & Brokers in the Medicare Advantage Space," April 15, 2024
- "OIG Confirms the Broad Protection of Employee Safe Harbor," October 16, 2023
- "CMS Updates List of Telehealth Services for CY 2023," February 28, 2023
- "OIG Blesses Gift Cards for Patient Engagement with Education Tool," August 22, 2022
- "Supreme Court Decision in *Dobbs v. Jackson Women's Health Organization* Overturns 50 Years of Precedent on Abortion Laws and Rights," July 1, 2022
- "California District Court Finds that EKRA Applies to Compensation Methodologies for Labs' Employed Marketers Who Market to Physicians," June 29, 2022
- "Supreme Court Saves Hospitals from \$1.6B Cut to 340B Program," June 20, 2022
- "Top 5 Legal Issues in Digital Health to Watch for in 2022," February 1, 2022

- "Debate Continues Around Scope of Practice Expansion for APPs," December 13, 2021
- "D.C. Circuit Gives New Life to CMS Overpayment Rule," August 17, 2021
- "Physician Group Practices Take Heed – January 1, 2022 Deadline Approaches for Compliance with CMS' Recent Changes to Permissible "Group Practice" Compensation Methodologies," August 12, 2021
- "Site-Neutral Payments Stand: SCOTUS Declines to Hear AHA Appeal, Preserving Lower Payments to Off-Campus Provider-Based Departments," July 8, 2021
- "340B Drug Pricing Discount Program Update: HRSA Now Demands That Drug Manufacturers Provide 340B Discounts To Contract Pharmacies Amid Ongoing Litigation," July 2, 2021
- "CMS Proposes Repeal of Certain Cost Reporting Requirements from the IPPS Final Rule for 2021," May 21, 2021
- "Evaluation of Innovation Center Models," February 5, 2021
- "Contract Pharmacies and the 340B Drug Discount Program: New Litigation and an Advisory Opinion Point to Ongoing Skirmishes on the 340B Battlefield," January 8, 2021
- "Analysis of OIG's New and Revised Regulatory Safe Harbors to the Federal Health Care Program Anti-Kickback Statute and Beneficiary Inducement Prohibition." December 22, 2020
- "Critical Analysis and Practical Implications of CMS' Changes to the Stark Law's Implementing Regulations," December 11, 2020
- "New Criteria Established for the Overall Hospital Quality Star Rating," December 8, 2020
- "Big Changes for Health Care Fraud and Abuse: HHS Gifts Providers Updates to the Stark Law and the AKS, Just in Time for the Holidays," November 25, 2020
- "Trump Administration Finalizes The Transparency in Coverage Rule," November 12, 2020
- "The U.S. Court of Appeals Denies Rehearing on Cuts to 340B Drug Pricing Program," November 2, 2020
- "It's Official: Telehealth Benefits Have Been Expanded For Medicare Beneficiaries," August 10, 2020
- "A Shot Across the Bow of the Pharmaceutical Industry: President Trump Issues a Quartet of Executive Orders on Drug Pricing that Might Eventually (OR NEVER?) Take Effect," July 27, 2020
- "Reopening Challenges: FAQs On Preparing For Additional Waves Of COVID-19," July 23, 2020
- "Site-Neutral Payments Stand: D.C. Court of Appeals Overturns Ruling and Allows Lower Payments to Off-Campus Provider-Based Departments," July 23, 2020
- "CMS Updates Waivers, Provides More Flexibility for Providers Responding to COVID-19," May 1, 2020
- "Even in a Crisis, Stark Law Compliance Demands Attention: CMS Issues Explanatory Guidance on Stark Law Blanket Waivers," April 23, 2020
- "Telehealth and Online Prescribing: COVID-19 Triggers Changes to the Prescriber/Patient/Pharmacist Relationship," April 21, 2020
- "Summary of Key Provisions of Interim Final Rule: CMS Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency," April 9, 2020
- "CMS' Blanket Waiver of Stark Law Sanctions During the COVID-19 Outbreak: Opportunities and Limitations," March 31, 2020
- "Key Health Care Provisions of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act")," March 30, 2020

- "Bringing Clarity to Section 1135 and Other Waivers amid the COVID-19 Emergency," March 20, 2020
- "Dateline: Telehealth and COVID-19," March 17, 2020
- "Telehealth and Federal and State Government Responses to the Coronavirus Pandemic," March 16, 2020
- "CMS Issues Long-Awaited Draft Guidance for Hospital Co-Location with Other Hospitals or Healthcare Facilities," May 9, 2019
- "The Military Health Care Fraud and Abuse Prevention Program: The Department of Defense Issues Proposed Regulations regarding TRICARE and Civil Monetary Penalties," May 3, 2019
- "OIG Advisory Opinion No. 19-03: The OIG Puts the Healthcare Benefits of Free In-Home Care and the Risks of Patient Steering in the Balance," March 8, 2019
- "Government Puts Electronic Health Records Companies "on Notice" of Vigorous False Claims Act Enforcement," February 8, 2019
- "Compliance Risk Alert: Opioid Warning Letters issued by the U.S. Department of Justice Target Prescribers," February 6, 2019
- "The Eliminating Kickbacks in Recovery Act: An Altered Landscape for Financial Relationships with Clinical Laboratories" January 8, 2019
- "CMS' Medicare Advantage Overpayment Rule: Arbitrary, Capricious, and Vacated," September 7, 2018
- "Star Ratings and Future Measurement Concepts in the CY 2019 Final Call Letter," April 11, 2018
- "MACRA Quality Payment Program Final Rule: Implications for 2018 and Beyond," November 29, 2017
- "MACRA Update: How to Prepare for Changes in MIPS," September 8, 2017
- "More Telemedicine Food for Thought: Exception Five to the Haight Act's In-Person Examination Requirement," July 13, 2017
- "Giving Telemedicine More Room to Breathe: Recent and Pending State and Federal Actions in the World of Online Prescribing," July 10, 2017
- "The MACRA Final Rule: The Art of the Transition," October 18, 2016
- "The Overpayment Rule and the Implied False Claims Theory: "What You Don't Know Can Still Hurt You," July 13, 2016
- "Supreme Court Preserves But Significantly Changes 'Implied Certification' Theory of False Claims Act Liability," June 17, 2016

Media Mentions

What's Special About AI Risks and Remedies in Health Care?

Healthcare IT Today, 12.29.2023

Zealous for Wellness: How to Replace Hype with Data

Healthcare IT Today, 11.15.2023

CMS issues nursing home staff minimums rule

Modern Healthcare, 09.01.2023

Patient insured, but can't afford care? Seek terms with payer for a cost break
PartB News, 12.19.2022

Speaking Engagements

Guest Lecture, "Anti-Kickback Statute," Washington College of Law Summer Institute, June 22, 2015

Anti-Kickback Statute Boot Camp for Compliance Professionals, Health Care Compliance Association webinar,
Nov. 19, 2014

Stark Law Boot Camp for Compliance Professionals, Health Care Compliance Association webinar, Oct. 21, 2014

Events

WHLC Dobbs Series Part 1

Where are we now? Join us for a primer on state law post-Dobbs and recent developments.
Webinar, 07.12.2022

Fraud and Compliance Considerations for Telemedicine and Digital Health: Navigating the Emerging Landscape
Panel

Fraud and Compliance Forum 2021
10.01.2021

The Women in Healthcare Leadership Collaborative (WHLC) Presents: Stark Alert – Be Prepared for Fast
Approaching Changes to Group Practice Requirements
09.30.2021

WHLC and NAWL Present: Stark, AKS & Value-Based Care under the Biden Administration
02.25.2021

Food and Drug Law Institute's 2019 Enforcement, Litigation and Compliance Conference
Food and Drug law Institute
December 11-12, 2019

CMS Proposes Numerous Significant Changes to Stark Law Regulations, Including a Broad Exception for 'Value-
Based Arrangements': Practical Implications for Your Organization
Webinar
10.31.2019

Podcasts & Webinars

WHLC Dobbs Series Part 1 Where are we now? Join us for a primer on state law post-Dobbs and recent
developments.
07.12.2022

Stark Alert – Be Prepared for Fast Approaching Changes to Group Practice Requirements
09.30.2021

WHLC and NAWL's Webinar - Stuck on Stark: Where do HHS' New Rules on Value-Based Care Stand under the Biden Administration, and What does that Mean for Collaboration in the Industry?

02.25.2021

Telehealth Webcast Series Episode 2 - Revenue Cycle Considerations for Telehealth: Receiving Payment for Telehealth Services, Sheppard Mullin and Citrin Cooperman representatives

06.03.2020

Telehealth Webcast Series Episode 1 - Intro to Telehealth Maturity Model: Developing an Adaptable Telehealth Strategy

05.08.2020

Practices

Corporate

Digital Health

False Claims Act

Governmental Practice

Healthcare

Women in Healthcare Leadership Collaborative

Industries

Healthcare

Education

J.D., Harvard Law School, 2012, *magna cum laude*

A.M., Harvard Graduate School of Arts and Sciences, Health Policy, 2015

B.A., University of Virginia, 2006, *with highest distinction*

Admissions

Virginia

District of Columbia