



## Amy H. Kearbey

Partner

Washington, DC  
+1 202-282-5677

Amy is a health care fraud and abuse lawyer who draws on her experience as a former attorney in the Office of Counsel to the Inspector General in the Department of Health and Human Services and her years in private practice to provide a unique and practical perspective to companies throughout the health care sector.

Amy focuses her practice on health care regulatory counseling, compliance, and defense. She has extensive experience advising organizations regarding the Anti-Kickback Statute, the Physician Self-Referral Law (commonly known as the Stark Law), the Civil Monetary Penalties Law, and Medicare program requirements. She works with stakeholders throughout the health care sector, including health systems, drug and device manufacturers, and digital health companies to structure compensation arrangements, develop business models, manage internal investigations and government disclosures, and navigate government investigations and enforcement actions under the False Claims Act. Her experience includes value-based care, patient assistance programs, and providing tools, support, and incentives to patients.

After several years in private practice, Amy served as senior counsel in the Office of Counsel to the Inspector General (OIG) at the Department of Health and Human Services. In that role, Amy provided legal analysis and advice to OIG and the Department of Justice (DOJ) regarding the Anti-Kickback Statute and the Civil Monetary Penalties Law in connection with policy development and OIG/DOJ investigations and enforcement actions. She also drafted

several OIG Advisory Opinions and represented OIG in associated legal matters. During her tenure, Amy was a member of the team that crafted the new safe harbors for value-based care as part of the Regulatory Sprint to Coordinated Care, and she advised on OIG's guidance modernization initiative.

## Key Matters

*Some of the experience represented below may have been handled at a previous firm.*

- Served as regulatory counsel to several large, integrated delivery systems on matters relating to physician compensation and compliance with the Stark Law, federal Anti-Kickback Statute and other health care regulatory compliance matters
- Counseled an institutional provider on policies and procedures relating to patient support services, including financial assistance and transportation
- Counseled a provider in obtaining resolution of potential violations of the Stark Law and the federal Anti-Kickback Statute through the OIG Self-Disclosure Protocol
- Obtained a favorable OIG Advisory Opinion regarding cost-sharing subsidies to subjects in a clinical trial conducted pursuant to the Medicare Coverage with Evidence Development program
- Evaluated and addressed compliance issues raised during due diligence of transactions involving a wide range of health care stakeholders, including hospitals and health systems, physician practices, and digital health companies
- Advised a Fortune 500 company on key health care regulatory matters in connection with a new business line in the health care sector
- Served as regulatory counsel to a trial team in an intervened *qui tam* matter that resulted in negotiating the settlement of FCA allegations constituting more than US\$1B in alleged damages in *United States ex rel. Kunz v. Halifax Health, et al.* (M.D. Florida 2014)
- Represented hospitals in proceedings before the Provider Reimbursement Review Board relating to Medicare reimbursement

## Recognitions

- Office of Inspector General, Award for Excellence in Promoting Quality, Safety, and Value, 2021 (Regulatory Sprint to Coordinated Care Team)
  - Office of Inspector General, Award for Excellence for Law and Legislation, 2021 (HHS OIG Regulatory Sprint Team)
  - *Super Lawyers* "Rising Star" – 2014
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## Activities

- American Health Law Association, Member
  - District of Columbia Bar Association, Member in Good Standing
  - North Carolina Bar Association, Member in Good Standing
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# Credentials

## EDUCATION

Amy received her J.D. from Duke University School of Law in 2005, where she was Executive Editor of *Duke Law and Technology Review* and president of the Health Law Society. Amy received her A.B. in government, with a minor in public policy, from Dartmouth College in 2001.

## ADMISSIONS

- District of Columbia
- North Carolina

## Related Insights & News

Amy is a frequent speaker at conferences and webinars hosted by the American Health Law Association (AHLA), the Health Care Compliance Association (HCCA), and the Health Law Section of the American Bar Association (ABA), and has co-authored articles on a wide range of topics relating to health care regulatory issues. Select thought leadership includes the following recent presentations and publications:

## PUBLICATIONS

- ["E.D. Virginia Endorses Broad Interpretation of Anti-Kickback Statute,"](#) Government Program Fraud, False Claims Act & Qui Tam Litigation Playbook, Co-author, April 17, 2024
- ["Supreme Court's False Claims Ruling Leaves Plenty to Litigate,"](#) Bloomberg Law, Co-author, Jun. 13, 2023
- ["8th Circ. Ruling Raises Bar for Anti-Kickback FCA Claims,"](#) Law360, Co-author, Jun. 10, 2022

## SPEAKING ENGAGEMENTS

- "Health System Acquisitions of Physician Practices: Navigating Compliance," AHLA 2022 Fraud and Compliance Forum, Speaker, Sept. 29, 2022
- "Anti-Kickback and Stark Law Developments: Where Are We Now and Where Are We Going?" HCCA 25th Annual Compliance Institute, Speaker, Apr. 22, 2021
- "Real Talk: How the Revised Stark and AKS Rules Will Impact Health Industry Compliance," ABA, Speaker, Jan. 12, 2021
- "Primer: The Stark Law, The Anti-Kickback Statute, and the CMP Law," AHLA 2020 Fraud and Compliance Forum, Speaker, 2020

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## SEMINAR/CLE

2024 Health Care & Life Sciences Summit

JUNE 4, 2024

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## BLOG

E.D. Virginia Endorses Broad Interpretation of Anti-Kickback Statute

APRIL 17, 2024

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## **IN THE MEDIA**

Amy Kearbey Discusses HHS-OIG Advisory Opinion on Physician Retirement Offer with Law360

JANUARY 4, 2024

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## **IN THE MEDIA**

Amy Kearbey Discussed HHS-OIG Advisory Opinion on Physician-Employee Bonuses with Law360

OCTOBER 16, 2023

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## **SEMINAR/CLE**

2023 Health Care & Life Sciences Summit

SEPTEMBER 21, 2023

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## **BLOG**

DOJ Continues to Crack Down on Health Care Fraud Violations, Announcing Convictions and Enforcement Activity

AUGUST 14, 2023

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## **BLOG**

June 2023 FCA Settlement Wrap-Up: DOJ Continues to Crack Down on Health Care Fraud

AUGUST 14, 2023

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## **BLOG**

Understanding SuperValu: Scienter in FCA Claims Hinges on Subjective Beliefs

JUNE 15, 2023

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## **SEMINAR/CLE**

Winston & Strawn's Product & Mass Torts Summit 2023

JUNE 14, 2023

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## **CLIENT ALERT**

CMS Issues Final Rule on Medicare Advantage RADV Audits Amid Increased Program Scrutiny

FEBRUARY 13, 2023

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## **SPONSORSHIP**

Winston & Strawn Hosts San Francisco Health Care Cocktail Reception

JANUARY 10, 2023

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## **BLOG**

OIG Issues Telemedicine Special Fraud Alert: Important Considerations for Telemedicine Companies and Practitioners

AUGUST 10, 2022

# Capabilities

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Government Investigations, Enforcement & Compliance

Government Program Fraud, False Claims Act & Qui Tam Litigation

Compliance Programs

Transactions

Health Care

Medical Devices

Life Sciences